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**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA**

JOIMAX, INC., a Delaware corporation,

Plaintiff,

vs.

SURGICAL ORTHOPEDIC IMPLANTS, INC. d/b/a MAXSPINE, a Florida corporation,

Defendant.

Case No.:

**COMPLAINT FOR:**

**(1) PATENT INFRINGEMENT;**
**(2) BREACH OF CONTRACT;**
**(3) FEDERAL TRADEMARK INFRINGEMENT;**
**(4) FEDERAL TRADE DRESS INFRINGEMENT;**
**(5) FEDERAL FALSE DESIGNATION OF ORIGIN;**
**(6) FEDERAL TRADEMARK DILUTION;**
**(7) CALIFORNIA INTENTIONAL INTERFERENCE WITH CONTRACTUAL RELATIONS;**
**(8) CALIFORNIA INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC RELATIONS;**
**(9) CALIFORNIA TRADEMARK INFRINGEMENT;**
**(10) CALIFORNIA TRADEMARK DILUTION; AND**
**(11) CALIFORNIA UNFAIR COMPETITION**

**DEMAND FOR JURY TRIAL**

Plaintiff Joimax, Inc. ("Joimax") hereby alleges as follows:

## PARTIES

1. Joimax is a corporation organized and existing under the laws of the State of Delaware and doing business in the State of California. At all relevant times, Joimax has been a subsidiary of Joimax GmbH and an owner by assignment of all rights, title, and interest in the below-described patents and trademarks. Joimax's principal place of business is located at 14 Goodyear, Suite 145, Irvine, CA 92618.

2. Defendant Surgical Orthopedic Implants, Inc. dba MaxSpine ("MaxSpine" and/or "Defendant") is a corporation organized and existing under the laws of the State of Florida and doing business in the State of California. Defendant's principal place of business is located at 4215 SW High Meadows Ave., Palm City, Florida 34990.

## NATURE OF THE ACTION

3. This is a civil action for patent infringement, breach of contract, federal and state trademark infringement, federal and state trademark dilution, federal and state unfair competition, federal trade dress infringement, federal false designation of origin, state intentional interference with contractual relations, and state intentional interference with prospective economic relations.

## JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action under the laws of the United States, 35 U.S.C. § 271, 28 U.S.C. §§ 1331 and 1338(a), and 15 U.S.C. §§ 1114, 1121, and 1125. This action also alleges trademark dilution, trademark infringement, intentional interference with contractual relations, and intentional interference with prospective economic relations in violation of state and common law. This Court has jurisdiction over these claims under 28 U.S.C. §§ 1338(b) and 1367(a).

5. This Court has personal jurisdiction over Defendant because it has committed one or more of the below-described infringing acts and torts in California and in this district, and it has a continuous, systematic, and substantial presence in California and in this district including by selling and offering for sale the below-described infringing products in California and in this district, as well as by selling those products into the stream of commerce knowing they would be sold in California and

in this district. Finally, this Court has personal jurisdiction over this action under section 22, paragraph III of the below-defined and attached Distribution Agreement.

6. Venue in this Court is proper under 28 U.S.C. § 1391 because a substantial part of the events and omissions giving rise to these claims arose in this district, and Defendant "resides" in this district because this Court has personal jurisdiction. Venue is also proper under 28 U.S.C. § 1400(b) because Defendant committed the below-discussed acts of infringement in this district. Indeed, Defendant's website www.maxspine.com markets Joimax's products and infringing products and is interactive and available to consumers in this district. Finally, venue is proper in this district under section 22, paragraph III of the below-defined and attached Distribution Agreement.

## BACKGROUND ALLEGATIONS

7. Joimax is a leading developer and marketer of complete systems for endoscopic minimally invasive spinal surgery. In procedures for herniated discs, stenosis, pain therapy, or spinal stabilization treatment, surgeons utilize Joimax products to operate through small incisions via tissue and muscle-sparing corridors through natural openings into the spinal canal. Joimax produces and markets a number of products for these purposes.

8. Joimax also regularly enters into distribution agreements, in which Joimax grants distributors the exclusive right to distribute its products to medical centers in certain territories. These agreements contain obligations that distributors not interfere with and respect Joimax's intellectual property rights, including the know-how regarding their products. They also contain non-competition provisions, confidentiality provisions, and various other protections for Joimax's intellectual property and to maintain its competitive advantage.

9. On June 24, 2016, Joimax entered into a distribution agreement with Defendant to distribute its registered TESSYS Instrument System (the "TESSYS System") and accompanying TESSYS Disposable Access Kit (the "Disposable Kit") (the "Distribution Agreement"). (A true copy of the Distribution Agreement is attached as **Exhibit "A."**) The TESSYS System is a Joimax-logo-marked metal bin that contains more than 50 special metal instruments for consistent use by surgeons and medical centers for minimally invasive spinal surgery.

10. The Disposable Kit is a separate sterile kit that contains all necessary disposable products for use with the TESSYS System, including special color-coded reamers to insert into Joimax products per use. These sterile reamers, and more precisely the TESSYS Crown Reamers with green, yellow and red plastic connectors, are used for bone-reaming and ensure that no re-sterilization takes place because the plastic melts at seventy degree Celsius (70°C) (the "Reamers"). (A true image of the Reamers is depicted in the photograph attached as **Exhibit "B."**) This prevents re-use in surgery because the Reamers no longer fit into the Joimax medical devices.

**JOIMAX'S PATENTS**

11. The Reamers are the subject of the alleged patent infringement by Defendant. Joimax is the owner by assignment of all right, title, and interest in four separate patents that encompass various features of the Reamers. Each of the four patents and Defendant's alleged infringement of the patents are discussed more particularly below.

12. On September 18, 2012, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued United States Patent No. 8,267,937 (the "'937 Patent"), entitled "Method for determining a tooth period length of a bone milling cutter." Joimax, through its parent company Joimax GmbH, is the owner by assignment of all right, title, and interest in the '937 Patent. (A true copy of the '937 Patent is attached as **Exhibit "C."**)

13. On May 28, 2013, the USPTO duly and lawfully issued United States Patent No. 8,449,546 (the "'546 Patent"), entitled "Spine cutter." Joimax, through its parent company Joimax GmbH, is the owner by assignment of all right, title, and interest in the '546 Patent. (A true copy of the '546 Patent is attached as **Exhibit "D."**)

14. On January 7, 2014, the USPTO duly and lawfully issued United States Patent No. 8,623,021 (the "'021 Patent"), entitled "Facet joint reamer." Joimax, through its parent company Joimax GmbH, is the owner by assignment of all right, title, and interest in the '021 Patent. (A true copy of the '021 Patent is attached as **Exhibit "E."**)

15. On September 2, 2014, the USPTO duly and lawfully issued United States Patent No. 8,821,378 (the "'378 Patent"), entitled "Device and method for minimally invasive spinal

intervention." Joimax is the owner by assignment of all right, title, and interest in the '378 Patent. (A true copy of the '378 Patent is attached as **Exhibit "F."**)

16. The '937 Patent, the '546 Patent, the '021 Patent, and the '378 Patent are all directed to the Reamers and may be collectively referred to as the "Asserted Patents." Defendant received written notice of Joimax's intellectual property rights in the Asserted Patents as early as Defendant's execution of the Distribution Agreement, which occurred on June 24, 2016.

## JOIMAX'S TRADEMARKS

17. Joimax's marks located on the metal bins containing the TESSYS System and the related word and service marks for "Joimax" and "TESSYS" are the subject of the alleged trademark infringement. Joimax, through its parent company Joimax GmbH, is also the owner by assignment of all right, title, and interest into the trademarks that encompass protect its rights surrounding the marks "Joimax" and "TESSYS."

18. Trademark Registration No. 3,302,672 (the "'672 Mark") was registered with the USPTO on October 2, 2007 on the Principal Register. The '672 Mark for the word mark, "Joimax," is associated with various medical goods and services, including surgical instruments, medical cutting devices, and all instruments located in the TESSYS System and Disposable Kit, including the Reamers. (A true copy of the certificate of registration of the '672 Mark is attached as **Exhibit "G."**)

19. Trademark Registration No. 3,619,500 (the "'500 Mark") was registered with the USPTO on May 12, 2009 on the Principal Register. The '500 Mark for the word mark, "TESSYS," is associated with various medical goods and services, including surgical instruments, medical cutting devices, and all instruments located in the TESSYS System and Disposable Kit, including the Reamers. (A true copy of the certificate of registration of the '500 Mark is attached as **Exhibit "H."**)

20. The '672 Mark and the '500 Mark may be collectively referred to as the "Joimax Marks." The Joimax Marks have not been abandoned, canceled, or revoked. Both of the Joimax Marks constitute enforceable trademarks that uniquely identify, among other things, the origin of, and Joimax's authorization and sponsorship for, all items located in the metal bins containing the TESSYS System and the Disposable Kit.

21. The widespread use and display of each of the Joimax Marks as a distinctive trademark identifying, among other things, the TESSYS System, Disposable Kit, and related surgical and medical products has resulted in the following: (i) the public has come to recognize and identify products bearing the Joimax Marks as emanating from Joimax; (ii) the public recognizes that products bearing any of the Joimax Marks constitute high-quality products that conform to Joimax's specifications; and (iii) each of the Joimax Marks has established strong secondary meaning and extensive goodwill.

**JOIMAX'S TRADE DRESS**

22. Joimax also manufactures, sells, and makes available for distribution medical instruments under the trademarks "Joimax®" and "TESSYS®" bearing distinctive trade dress in the overall design of and logo on the metal bin for the TESSYS System and Disposable Kit (the "Joimax Trade Dress"). (A true image of a the metal bin for the TESSYS System and the Disposable Kit bearing the Joimax Trade Dress is depicted in the photograph attached as **Exhibit "I."**)

23. The widespread use and display of the Joimax Trade Dress in association with, among other things, the TESSYS System, Disposable Kit, and related surgical and medical products has resulted in the following: (i) the public has come to recognize and identify products bearing the Joimax Trade Dress as emanating from Joimax; (ii) the public recognizes that products bearing any of the Joimax Trade Dress constitute high-quality products that conform to Joimax's specifications; and (iii) each of the Joimax Trade Dress has established strong secondary meaning and extensive goodwill.

24. Defendant received written notice of Joimax's intellectual property rights in the Joimax Marks and Joimax Trade Dress as early as Defendant's execution of the Distribution Agreement, which occurred on June 24, 2016.

**DEFENDANT'S INFRINGING PRODUCTS AND INTERFERENCE**

25. As referenced above, Defendant entered into the Distribution Agreement with Joimax to distribute the TESSYS System and Disposable Kit to various surgeons and medical centers, which were Joimax-generated leads and customers. In its capacity as a distributor, Defendant ordered Joimax's medical products and had access to the Reamers, embodying the features of the Asserted

Patents. Defendant also had access to the TESSYS System and Disposable Kit bearing the Joimax Marks and Joimax Trade Dress prior to their ultimate sale to the surgeons and medical centers.

26. Upon information and belief, Defendant received the above Joimax products and used them to develop and manufacture identical, all-metal, and purportedly re-usable counterfeit versions of the Reamers (the "Infringing Reamers"). (A true image of the Infringing Reamers is depicted in the photograph attached as **Exhibit "J."**) The Infringing Reamers are identical copies of the Reamers, except that Defendant replaced the plastic connectors with identical metal connectors, so that they could be re-usable. This constituted a blatant infringement on Joimax's rights in the Asserted Patents.

27. Defendant then placed the Infringing Reamers in the metal bins containing the TESSYS System, which bear the Joimax Marks and Joimax Trade Dress, and repeatedly sold them to the ultimate consumers. Defendant marketed and sold the TESSYS System, with the added inclusion of the Infringing Reamers, to Joimax's customers, including surgeons and medical centers, as if they were Joimax-approved medical devices. Joimax alleges that at least sixty-nine (69) surgeons at fifteen (15) hospitals received the Infringing Reamers.

28. Upon information and belief, Defendant did not notify any of the surgeons or medical centers of the true manufacturer of the Infringing Reamers. Defendant also marketed the TESSYS System with the Infringing Reamers at increased cost, while communicating to consumers that they would no longer need the Disposable Kit, dramatically increasing Defendant's profit margins. Defendant did so without prior approval from the United States Food and Drug Administration ("FDA") and without regard to the serious harm the Infringing Reamers would cause surgical patients.

29. From June 2016 to January 2017, Joimax did not have knowledge of Defendant's wrongdoing. Joimax continually attempted to contact Defendant for details on how Defendant was representing Joimax in the marketplace. Defendant refused to share any information about where and how it was representing Joimax and details about distribution of Joimax products pursuant to the Distribution Agreement. Then, in January 2017, Joimax finally became aware of the above wrongful conduct and terminated the Distribution Agreement.

30. On February 1, 2017, Joimax sent a letter to Defendant regarding the infringement of the Asserted Patents and other wrongful conduct. Joimax also requested corrective measures be taken by Defendant. Defendant substantively responded to this letter on February 20, 2017, denying any infringement. Joimax and Defendant then exchanged several additional letters about the above issues without resolving the dispute.

31. Upon information and belief, Defendant continues to manufacture, market, and sell the Infringing Reamers in the manner described above, infringing on the Asserted Patents, the Joimax Marks, and the Joimax Trade Dress. Several of Joimax's existing customer accounts both inside and outside Defendant's exclusive territory under the Distribution Agreement have been the subject of interference as a result.

## FIRST COUNT

**(For Patent Infringement [35 U.S.C. § 271] Against Defendant)**

32. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

33. In acting or failing to act as described above, Defendant has and continues to knowingly, intentionally, and willfully directly infringe, engage in acts of contributory infringement, and/or induce the infringement of each of the Asserted Patents by directly and/or indirectly manufacturing, using, selling, and/or offering for sale the Infringing Reamers, which are covered by at least one claim of each of the Asserted Patents.

34. Due to Defendant's access to the TESSYS System, the Disposable Kit, and the Reamers through the Distribution Agreement, Defendants had actual and/or constructive knowledge of each of the Asserted Patents, and its actions constitute willful and intentional infringement of the Asserted Patents. Joimax also marks its products pursuant to 35 U.S.C. § 287.

35. Defendant's acts of infringement of the Asserted Patents were undertaken and continue to be undertaken without permission or license from Joimax.

36. Upon information and belief, Defendant derived and received, and will continue to derive and receive, gains, profits, and advantages from the above-described acts of infringement in an

amount not presently known to Joimax. Joimax has been damaged as a result of Defendant's infringing conduct and is entitled to monetary relief in an amount to be determined at trial.

37. Joimax will also continue to suffer severe and irreparable harm for which Joimax has no adequate remedy at law. As a result, Joimax seeks a permanent injunction from this Court prohibiting Defendant from infringing on the Asserted Patents.

38. Joimax is also entitled to its attorneys' fees and costs upon prevailing in this action due to the exceptional nature of this dispute under 35 U.S.C. § 285.

39. Further, Joimax is entitled to treble damages and/or exemplary damages because of Defendant's willful conduct under 35 U.S.C. § 284.

## SECOND COUNT

**(For Breach of Contract Against Defendant)**

40. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

41. On or about June 24, 2016, Joimax and Defendant entered into the Distribution Agreement. Defendant's obligations under the Distribution Agreement included without limitation:

41.1. Defendant shall refrain from any competition with Joimax, including sale of competitive products of manufacturers other than Joimax;

41.2. Defendant acknowledges Joimax's intellectual property rights and shall be enjoined from reproducing or copying the medical products;

41.3. Defendant shall keep and update records and cooperate with Joimax to engage in corrective measures and re-calls of the medical products;

41.4. Defendant shall notify Joimax of replacements of safety-relevant medical products; and

41.5. Defendant shall not sell Joimax's medical products to consumers outside the exclusive territory.

42. Joimax performed each and every obligation owed under the Distribution Agreement, except those obligations that Joimax was prevented from performing due to Defendant's wrongful conduct, as described more particularly below.

43. In acting or failing to act as described above, Joimax alleges upon information and belief that Defendants breached their obligations by: (i) competing with Joimax and selling and marketing the Infringing Reamers, which are identical copies of the Reamers; (ii) selling Joimax's medical products with the Infringing Reamers to consumers outside the exclusive territory and interfering with Joimax's current accounts; (iii) failing to keep and update records and cooperate with Joimax to engage in corrective measures to recall the Infringing Products; and (iv) not notifying Joimax of the replacement of the Reamers with the Infringing Reamers.

44. As a direct and proximate result of the breaches of the Distribution Agreement by Defendant, Joimax alleges upon information and belief that it has been damaged and is entitled to monetary relief in an amount to be determined at trial.

**THIRD COUNT**

**(For Federal Trademark Infringement [15 U.S.C. § 1114] Against Defendant)**

45. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

46. In acting or failing to act as described above, Defendant is manufacturing, selling, offering for sale, and/or distributing TESSYS Systems with Infringing Reamers that bear one or more of the Joimax Marks without Joimax's consent.

47. Long after Joimax's adoption and use of the Joimax Marks, after federal registration of both of the Joimax Marks, and after both of the Joimax Marks had become ubiquitous in the industry, Defendant has affixed and used one or more of the Joimax Marks without Joimax's consent in a manner that infringes upon Joimax's rights in the Joimax Marks in violation of 15 U.S.C. § 1114.

48. Without Joimax's consent, Defendant uses in commerce marks that are confusingly similar to the Joimax Marks in connection with the sale, offering for sale, distribution or advertising of the TESSYS System, and particularly with the inclusion of the Infringing Reamers in the TESSYS System, in a manner which is likely to cause confusion, to cause mistake, or to deceive.

49. Upon information and belief, Defendant engaged in the above wrongful conduct with the intent to unfairly compete with Joimax, to trade upon Joimax's reputation and goodwill by causing

confusion and mistake among consumers, surgeons, and medical centers, and to deceive the public into believing that Defendant's products, and in particular the Infringing Reamers, are associated with, sponsored by, originated from, or are approved by Joimax, when they are not.

50. Defendant's activities constitute willful and intentional infringement of the Joimax Marks in total disregard for Joimax's proprietary rights, and were done despite Defendant's knowledge that the use of the Joimax Marks was and is in direct contravention of Joimax's rights.

51. Upon information and belief, Defendant derived and received, and will continue to derive and receive, gains, profits, and advantages from the above-described acts of infringement in an amount not presently known to Joimax. Joimax has been damaged as a result of Defendant's infringing conduct and is entitled to monetary relief in an amount to be determined at trial.

52. Joimax will also continue to suffer severe and irreparable harm for which Joimax has no adequate remedy at law. As a result, Joimax seeks a permanent injunction from this Court prohibiting Defendant from infringing on the Joimax Marks.

## FOURTH COUNT

**(For Federal Trade Dress Infringement [15 U.S.C. § 1125(a)] Against Defendant)**

53. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

54. As a result of the widespread use and display of the Joimax Trade Dress, the trade dress has acquired a secondary meaning to potential purchasers, surgeons, and medical centers, in that they have come to associated the TESSYS System and the metal bin containing those medical instruments with Joimax.

55. Subsequent to Joimax's use and adoption of the Joimax Trade Dress, Defendant has developed, advertised, and sold the Infringing Reamers by placing them in the metal bins with the TESSYS System, using trade dress that is confusingly similar to Joimax's trade dress. Defendant's distributed TESSYS System with the inclusion of the Infringing Reamers is identical to the design and display of the Joimax Trade Dress.

56. Defendant's use of these features in connection with its Infringing Reamers constitutes a false designation of origin that is likely to cause confusion, to cause mistake, or to deceive as to the affiliation, connection, or association of Defendant with Joimax.

57. Defendant's false designation of origin, when used in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of Defendant's goods by representing to consumers that Defendant's products have the same nature, characteristics, qualities, and origin as Joimax's products.

58. Upon information and belief, Defendant's acts of trade dress infringement were undertaken willfully and will fully knowledge of the falsity of such designation of origin and false descriptions or representations, and with the express intent to cause confusion, to mislead the public, and to deceive the public.

59. Upon information and belief, Defendant derived and received, and will continue to derive and receive, gains, profits, and advantages from the above-described acts of infringement in an amount not presently known to Joimax. Joimax has been damaged as a result of Defendant's infringing conduct and is entitled to monetary relief in an amount to be determined at trial.

60. Joimax will also continue to suffer severe and irreparable harm for which Joimax has no adequate remedy at law. As a result, Joimax seeks a permanent injunction from this Court prohibiting Defendant from infringing on the Joimax Trade Dress.

## FIFTH COUNT

**(For Federal False Designation of Origin [15 U.S.C. § 1125(a)] Against Defendant)**

61. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

62. Defendant's use of the Joimax Marks without Joimax's consent constitutes a false designation of origin, false or misleading description of fact or false or misleading representation of fact, which is likely to cause confusion, to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of its goods or commercial activities by another person in violation of 15 U.S.C. § 1125(a).

63. Such conduct by Defendant is likely to confuse, mislead, and deceive Defendant's customers, purchasers, and members of the public as to the origin of the Joimax Marks or cause said persons to believe that Defendant and/or its products, and in particular the Infringing Reamers, have been sponsored, approved, authorized, or licensed by Joimax or are in some way affiliated or connected with Joimax, all in violation of 15 U.S.C. § 1125(a).

64. Upon information and belief, Defendant's actions were undertaken willfully and will fully knowledge of the falsity of such designation of origin and false descriptions or representations, and with the express intent to cause confusion, to mislead the public, and to deceive the public.

65. Upon information and belief, Defendant derived and received, and will continue to derive and receive, gains, profits, and advantages from the above-described acts of false designation or origin in an amount not presently known to Joimax. Joimax has been damaged as a result of Defendant's conduct and is entitled to monetary relief in an amount to be determined at trial.

66. Joimax will also continue to suffer severe and irreparable harm for which Joimax has no adequate remedy at law. As a result, Joimax seeks a permanent injunction from this Court prohibiting Defendant from continuing its false designation of origin and/or false or misleading descriptions of fact and/or misleading representations of fact.

## SIXTH COUNT

**(For Federal Trademark Dilution [15 U.S.C. § 1125(c)] Against Defendant)**

67. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

68. The TESSYS System, Disposable Kit, and other medical products with the Joimax Marks have been widely advertised, promoted, and distributed to the purchasing public, including surgeons and medical centers, throughout the United States and the world.

69. Medical products such as the TESSYS System and Disposable Kit sold under the Joimax Marks, by reason of their style, design, and quality, have come to be known to the purchasing public throughout the United States as representing FDA-approved medical products of high quality,

which are sold under good merchandizing and customer service conditions. As a result, the Joimax Marks, and the goodwill associated therewith, are of great value to Joimax.

70. By virtue of the wide renown acquired by the Joimax Marks, coupled with the national and international distribution and extensive sale of various products distributed under these trademarks, each of the Joimax Marks has become famous.

71. Upon information and belief, Defendant's actions, and in particular the for-profit deception of placing the Infringing Reamers in the TESSYS System marked with the Joimax Marks, were done willfully with intent to exploit Joimax's reputation and dilute the Joimax Marks.

72. As a direct and proximate result of the trademark dilution by Defendant, Joimax alleges upon information and belief that it has been damaged and is entitled to monetary relief in an amount to be determined at trial.

73. Joimax will also continue to suffer severe and irreparable harm for which Joimax has no adequate remedy at law. As a result, Joimax seeks a permanent injunction from this Court prohibiting Defendant from continuing its trademark dilution of the Joimax Marks.

## SEVENTH COUNT

**(For California Intentional Interference with Contractual Relations Against Defendant)**

74. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

75. At all relevant times, there existed contracts between Joimax and a wide variety of Joimax's customers, including surgeons and medical centers, as described more particularly above, all of which Defendant was aware. Specifically, Joimax has existing contracts and active accounts with medical centers and surgeons both inside and outside the territories marked in the Distribution Agreement. Joimax alleges upon information and belief that Defendant intended to use such knowledge to interfere with and disrupt those contracts.

76. Upon information and belief, Defendant prevented Joimax's performance under its contracts, and/or otherwise made such performance under its contracts more expensive or difficult, by intentionally interfering with Joimax's contracts.

77. In so doing, Defendant's conduct constituted a substantial factor in causing harm to Joimax's business, finances, and reputation, as it relates to the above contracts.

78. As a direct and proximate result of the intentional interference by Defendant, Joimax alleges upon information and belief that it has been damaged and is entitled to monetary relief in an amount to be determined at trial.

79. In acting or failing to act as described above, Defendant acted with oppression, fraud, and malice, and thus Joimax is entitled to an award of punitive damages for the sake of example and by way of punishment.

## EIGHTH COUNT

**(For California Intentional Interference with Prospective Economic Relations Against Defendant)**

80. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

81. At all relevant times, Joimax was in an economic relationship with a wide variety of surgeons and medical centers, as described more particularly above, which probably would have resulted in an economic benefit to Joimax.

82. In acting or failing to act as described above, Joimax alleges upon information and belief that Defendant knew of the above economic relationships and intended to disrupt those relationships. Joimax further alleges that these economic relationships were disrupted due to Defendant's wrongful and fraudulent conduct.

83. In so doing, Defendant's conduct constituted a substantial factor in causing harm to Joimax's business, finances, and reputation.

84. As a direct and proximate result of the intentional interference by Defendant, Joimax alleges upon information and belief that it has been damaged and is entitled to monetary relief in an amount to be determined at trial.

85. In acting or failing to act as described above, Defendant acted with oppression, fraud, and malice, and thus Joimax is entitled to an award of punitive damages for the sake of example and by way of punishment.

## NINTH COUNT

**(For California Trademark Infringement Against Defendant)**

86. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

87. In acting or failing to act as described above, Defendant has engaged in trademark infringement of the Joimax Marks under California common law. Defendant's acts are willful and deliberate and committed with knowledge that Defendant's unauthorized use of the Joimax Marks causes a likelihood of confusion.

88. Upon information and belief, Defendant derived and received, and will continue to derive and receive, gains, profits, and advantages from the above-described acts of infringement in an amount not presently known to Joimax. Joimax has been damaged as a result of Defendant's infringing conduct and is entitled to monetary relief in an amount to be determined at trial.

89. Joimax will also continue to suffer severe and irreparable harm for which Joimax has no adequate remedy at law. As a result, Joimax seeks a permanent injunction from this Court prohibiting Defendant from infringing on the Joimax Marks.

## TENTH COUNT

**(For California Trademark Dilution [Bus. & Prof. Code § 14247] Against Defendant)**

90. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

91. Joimax Trade Dress and Joimax Marks are widely recognized by the general public, and in particular surgeons and medical centers, as a designation of source of the medical products of Joimax. Joimax Trade Dress and Joimax Marks have become famous and distinctive.

92. After Joimax Trade Dress and Joimax Marks became famous and distinctive, Defendant began using in commerce, and continues to use in commerce, Joimax Trade Dress and Joimax Marks

in the sale of its Infringing Reamers, which is likely to cause dilution of the Joimax Trade Dress and Joimax Marks.

93. As a result, Joimax will suffer and will continue to suffer severe and irreparable harm for which Joimax has no adequate remedy at law. As a result, Joimax seeks a permanent injunction from this Court prohibiting Defendant from continuing its trademark dilution.

## ELEVENTH COUNT

**(For California Unfair Competition [Bus. & Prof. Code § 17200 et seq.] Against Defendant)**

94. Joimax repeats and incorporates by reference into this count the allegations set forth above as though fully set forth in this count.

95. In acting or failing to act as described above, Joimax alleges upon information and belief that Defendant engaged in unfair and/or fraudulent business practices as defined by Business and Professions Code section 17200 et seq.

96. This unfair competition includes without limitation Defendant's deceptive manufacture, sale, and marketing of the Infringing Reamers with Joimax's medical products, including the TESSYS System, to surgeons and medical centers.

97. As a direct and proximate result of the unfair competition by Defendant, Joimax alleges upon information and belief that it has been damaged and is entitled to monetary relief in an amount to be determined at trial.

98. Joimax is further entitled to injunctive relief to enjoin Defendant from continuing to unfairly compete with Joimax.

## PRAYER FOR RELIEF

WHEREFORE, Joimax respectfully prays that this Court enter judgment against Defendant as follows:

1. For an Order adjudging Defendant to have willfully infringed on each of the Asserted Patents;

2. For an Order enjoining Defendant from directly or indirectly infringing on each of the Asserted Patents;

3. For an accounting for all of Defendant's gains, profits, and advantages derived by Defendant's infringement on each of the Asserted Patents, and for an award of monetary damages adequate to compensate Joimax for the past infringement and any continuing or future infringement up until judgment is entered, in no event less than a reasonable royalty, costs, expenses, and pre-judgment and post-judgment interest for Defendant's infringement on each of the Asserted Patents;

4. For an award of damages and/or exemplary damages because of Defendant's willful conduct under 35 U.S.C. § 284;

5. For an Order that this is an exceptional case and for an award of attorneys' fees and costs under 35 U.S.C. § 285;

6. For an Order enjoining Defendant from infringing on the Joimax Marks and/or the Joimax Trade Dress, from falsely designating the origin of Defendant's goods, from unfairly competing with Joimax in any manner whatsoever, from causing a likelihood of confusion or injuries to Joimax's business reputation, and from manufacturing, using displaying, distributing, or selling any goods that infringe on or dilute any of the Joimax Marks or Joimax Trade Dress;

7. For an accounting for all of Defendant's gains, profits, and advantages derived by Defendant's infringement on each of the Joimax Marks and Joimax Trade Dress, and for an award of monetary damages adequate to compensate Joimax for the past infringement and any continuing or future infringement up until judgment is entered, in no event less than a reasonable royalty, costs, expenses, and pre-judgment and post-judgment interest for Defendant's infringement on each of the Joimax Marks and Joimax Trade Dress;

8. For an award of punitive damages according to proof (as to the 7th and 8th causes of action only);

9. For an award of general, special, compensatory, and/or consequential damages and lost profits with the exact amount to be proven at time of trial;

10. For an award of pre-judgment interest at the maximum legal rate in an amount to be proven at time of trial; and

11. For any other relief as the Court deems just and proper.

Dated: June 6, 2017

KUSHNER CARLSON, PC

By: _____
MICHAEL B. KUSHNER
MICHAEL S. VASIN
JONATHAN P. SCHMIDT
Attorneys for Plaintiff

**DEMAND FOR JURY TRIAL**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Joimax demands a trial by jury on all issues triable to a jury.

Dated: June 6, 2017

KUSHNER CARLSON, PC

By: _____
MICHAEL B. KUSHNER
MICHAEL S. VASIN
JONATHAN P. SCHMIDT
Attorneys for Plaintiff

# EXHIBIT "A"

# Distribution Agreement

**Between**

**Joimax, Inc.**
14 Goodyear, Suite 145
Irvine, California
92602
USA

Hereinafter called „**Manufacturer**"

And

**Company xxxx** Surgical Orthopedic Implants DBA MaxSpine
**Address xxx** 4215 SW High Meadow Ave
**Address xxx** Palm City FL 34990
**Tax ID xxxxx** 65-0890923
**Phone xxx** 772 263 2158
**Email xxxxx** fgolden1@gmail.com

Hereinafter called „**Distributor**"

The parties to the Agreement stipulate the following:

**§ 1 – Subject Matter of the Agreement**

I. Effective April 15, 2016 and limited to the term of Agreement, Manufacturer grants Distributor the exclusive right ("Exclusive Right") to distribute the products manufactured and/or distributed by Manufacturer being listed in detail in Appendix 1 (hereinafter referred to as "Products") and Appendix 2 (hereinafter referred to as "Territory" which will be defined as Specific Facilities and/or specific surgeons). Exclusive Right means that the manufacturer shall not grant to any third company or person the right to distribute the Products within the Territory. Areas outside the Territory are reserved to the Manufacturer or allocated by the Manufacturer to other Distributors.

II. Distributor shall purchase and distribute the Products in his own name and for his own account. By all possible means, he shall strive towards furthering sales of the Products effectively. Distributor shall not sell the Products to customers outside their established territory.

III. Distributor shall not be entitled to represent Manufacturer in legal terms.

IV. The distributor shall be obligated to procure the required general approval of the products by the competent authorities in the Territory according to the Laws applicable in the Territory. The general approval shall be issued in the name of the Manufacturer. Distributor shall inform Manufacturer on all requirements for the general approval in the Territory in-

cluding related costs. After approval of costs by Manufacturer, Distributor shall prepare all necessary steps including drafting the application. Joimax shall assist Distributor by providing Distributor with the necessary documents regarding the properties and conditions of the Products. Each party shall bear its own internal costs which are a result of the approval. All external costs which are a result of the approval will be shared equally.

**§ 2 – Rights of the Distributor**

I. Distributor shall be granted the right to use his status as Distributor for Manufacturer for promotional purposes and to act as official exclusive Distributor in the specified market. For these purposes, he shall use the following logo/text:

joimax
helping to heal patients

Distributed by

II. Distributor must use Manufacturer's promotional material. If new promotional material is added to the list, Manufacturer shall also provide Distributor with a free trial copy. The promotional material offered do not contain Manufacturer's addresses for ordering purposes but a marked free field which Distributor may use for inserting his own company logo and his address. All promotional materials not provided by the manufacturer, has to be previously approved by the manufacturer.

III. The distributor may attend national congresses in his territory and presents the latest product-line of the manufacturer.

IV. Manufacturer organizes workshops for Customers regarding the Products. If the distributor sends customers to the workshop, he must attend said workshop at his own expense.

**§ 3 – Obligations of the Distributor**

I. Distributor shall guarantee that his sales personnel (Medical Device Consultants) will be trained sufficiently in the operation of the Products, as the case may be by having them attend product trainings conducted by Manufacturer, at Distributor's own expense. Furthermore, he shall warrant maintaining the required training level through appropriate measures.

II. Distributor shall warrant that he will keep and update records (in paper or electronically) which at any time allow traceability of Products, i.e. identification of which Products were delivered to individual customers. Distributor shall observe data protection law. These records shall ensure that systematic re-calls of Products can be carried out anytime. In case of incidents of the Products that require corrective measures or re-calls of Products according to mandatory law Distributor shall be obligated to cooperate with Manufacturer and hand over to Manufacturer such records that Manufacturer needs for prompt and reliable performance of the corrective measures or re-calls of Products.

III. Distributor shall warrant to inform Manufacturer immediately (within 48 hours), comprehensively and in written form about the following events, providing contact data of the persons affected:

- Considerable deterioration of the state of health of a patient treated with one or more of Manufacturer's Products
- Bodily injury of a patient treated with one or more of Manufacturer's Products and/or bodily injury of operating staff resulting from their handling the Products
- Death of a patient treated with one or more of Manufacturer's Products and/or death of office staff as a result of the application of Manufacturer's Products

IV. Furthermore, Distributor is obliged to inform Manufacturer immediately , in written form and comprehensively about the following circumstances:

- All known customer complaints (about Products, returned Products etc.)
- All defects and deficiencies of Products or accompanying documentation detected or known by Distributor
- Replacements of safety relevant Products

V. The provisions of section II. To IV. Of this § 3 shall remain valid even after termination of this contract.

**§ 4 – Industrial Property Rights**

I. Manufacturer shall retain all copyrights as well as all industrial property rights including the know-how regarding Products. This applies especially to the software contained in the Products. Distributor shall be enjoined from reproducing or copying the Products either himself or through third parties. This obligation persists for any time after termination of this Agreement.

II. Distributor shall not register in his own name or claim any trade mark, trade name or any other distinguishing marks owned by Manufacturer or any other marks and names which are similar to those owned by Manufacturer. However, he may use marks, trade names and other distinguishing marks owned by Manufacturer within the framework of the stipulations of this Agreement. This authority expires automatically on termination of this Agreement, regardless of reason for termination. During sales negotiations with customers, Distributor shall be obliged to disclose that the Products are made by Manufacturer. He shall not be entitled to promote the Products as being manufactured by himself.

III. In no case Distributor shall be entitled to remove, conceal or obscure Manufacturer's trade marks from the Products or the promotional material.

**§ 5 – Competition**

I. MANUFACTURER ACKNOWLEDGES THAT DISTRIBUTOR SELLS OR DISTRIBUTES CERTAIN COMPETITIVE PRODUCTS AS SET FORTH ON Appendix 4 and AGREES THAT IT MAY CONTINUE TO DO SO IN AND OUT OF THE TERRITORY. DISTRIBUTOR, HOWEVER, SHALL REFRAIN FROM ANY COMPETITION AGAINST MANUFACTURER OTHER THAN AS SET FORTH ON Appendix 4. It shall be especially obliged to purchase the Products solely from Manufacturer during the term of this Agreement. IT SHALL NOT SELL OR DISTRIBUTE COMPETITIVE PRODUCTS OF MANUFACTURERS OTHER THAN THOSE LISTED ON EXHIBIT D, WITHIN THE TERRITORY, neither as authorised dealer, nor as sales agent or commission agent, neither take a share in such companies nor further them in any other way without express authorization from manufacturer. Furthermore, WITH THE EXCEPTIONS LISTED ABOVE, he shall neither manufacture nor distribute products which are directly competitive to the Products nor support third parties in doing so.

**§ 6 – Product and Sales Trainings**

The manufacturer offers regular product and marketing training. The Distributor shall participate on a regular basis at his own expense. Dates will be advised in advance.

**§ 7 – Prices and Price Changes**

I. Manufacturer shall provide Distributor regularly with updated price lists for the Products. The prices in these lists are net prices.

II. Manufacturer shall be entitled to change prices stated in paragraph 2 or to exchange price lists for updated versions. Amended prices are valid for all future orders and for all those Products. For all orders which were already placed but not delivered or invoiced as yet, the older price is binding. The extent of price reductions is at Manufacturer's discretion.

**§ 8 – Products and Product Changes**

I. Manufacturer shall inform Distributor about the current product portfolio on a regular basis.

II. Manufacturer shall be entitled to review and change the Products.

III. Furthermore, Manufacturer shall be entitled to change his product portfolio. Manufacturer shall give notice of such changes – especially the deletion of Products – to Distributor at least 2 months in advance in written form.

IV. DISTRIBUTOR SHALL BE ENTITLED TO CHOOSE TO DISCONTINUE DISTRIBUTION OF ANY OF THE PRODUCTS IN THE EVENT THAT MANUFACTURER IS UNABLE TO TIMELY DELIVER OR PROVIDE SUCH PRODUCTS IN RESPONSE TO DISTRIBUTOR'S NEEDS.

**§ 9 – Forecast & Targets**

I. Distributor shall inform Manufacturer on annual purchasing targets and of an equally annual plan. On the basis of these figures, the parties shall agree on new forecast figures and estimated purchase quantity for each subsequent year. Distributor agrees to keep Manufacturer informed of progress on sales leads targets and projects that involve Manufacturer's products.

**§ 10 – Orders and Deliveries**

I. The ordering and delivery of the Products shall take place on the basis of individual purchase contracts for which the General Terms & Conditions of Trade of Manufacturer ("Terms & Conditions") as amended in Appendix 3 apply. In the event of a change to the

Terms & Conditions, the distributor will be informed by the Manufacturer at least one (1) month prior to the taking effect of such change. In the event of differences between this contract and the Terms & Conditions, this contract shall prevail.

II. Distributor shall order Products in written form. Each order shall contain delivery address and required date of delivery. Both delivery address and required date of delivery may be changed retroactively by Distributor prior to dispatch, this in agreement with Manufacturer.

III. The purchase contract shall come into effect only on acceptance of the order of the Distributor by Manufacturer. Manufacturer may decline acceptance of the order in particular if Distributor violates terms and conditions of the contract or if Manufacturer is unable to meet the conditions of the order due to lack of production capacities or other reasons.

IV. Manufacturer shall be entitled to partial or premature deliveries according to the Terms & Conditions.

V. Delivery shall be Ex Works (Incoterms 2012) the plant of the Manufacturer unless otherwise agreed in writing.

**§ 11 – Terms of Payment**

I. Payments must be completed in advance.

The payment amount shall be transferred to the account specified by Manufacturer (in the United States) free of charges and without further deductions within the said term.

**§ 12 – Retention of Title / Coverage for Receivables / Credit Line**

I. The Products remain property of Manufacturer until payment from distributor is received. Clause IX of the Terms & Conditions remains unaffected.

**§ 13 – Warranty / Limitation of Claim**

I. The properties and conditions of the Products including its designated use, industry-standard and shelf life are those defined in the manuals and on the packaging. The Products comply with the legal requirements for such products in the United States. The Distributor bears the risk of compliance with specific legal requirements in the Territory and specific expectancies of customers in the Territory.

II. Distributor shall be obliged to inspect the Products for defects directly after delivery according to their local compliance laws.

III. In the event of justified warrantable and timely complaints Manufacturer shall be entitled to carry out supplementary performance, i.e. either removal of defects or supply Products free from defects, at his own option.

IV. Subject to the following provisions compensations claims asserted by Distributor as well as claims for reimbursement of useless expenses shall be barred, regardless of legal ground. This disclaimer of warranty shall not apply in the event of negligent or deliberate injury of life, body or health or in the event of gross negligent or deliberate damage of other objects of legal protection. Any claim for damage for violation of material contractual obligations shall be limited to foreseeable damages typical for this Agreement unless intent or gross negligence are on hand or liability for injury, body or health are assumed. The preceding stipulations shall not result in a change of burden of proof to Distributor's disadvantage.

V. The Manufacturer provides warranty in accordance with statutory warranty regulations as defined in this Agreement and the Terms & Conditions (**"Manufacturer's Conditions of Warranty"**). Manufacturer shall assume warranty towards Distributor's customers according to Manufacturer's Conditions of Warranty. The Distributor's customers shall acquire rights of claim of their own according to Manufacturer's Conditions of Warranty through

their purchases from Distributor. Distributor shall not be obliged to fulfil requirements arising from Manufacturer's Conditions of Warranty towards his customers.

VI. Distributor shall be entitled to exclude any warranty towards his customers. It shall rather be paramount that he refer them to the assertion of their rights regarding Manufacturer's Conditions of Warranty and, in this regard, agree with them the defence of failure to pursue remedies.

VII. The parties to this Agreement shall inform each other of epidemic defects without delay. After having obtained information about an epidemic defect Manufacturer shall immediately take all suitable technical measures to remedy the defect. An epidemic defect shall be defined as a defect which occurs with more than 10% of a specific Product in identical or similar manner.

**§ 14 – Term of Agreement**

I. The Agreement shall remain in effect until either party issues 30 day notice of termination. If the term of the agreement exceeds 5 years, the notice period for termination shall be 90 days.

II. In the event that the fifty percent or more of the shares in Manufacturer's company or the substantial assets of Manufacturer's scope of business covering the Products are sold to a third party, Manufacturer has the right to terminate the Agreement with a notice period of 12 weeks. Aside from the above, the Agreement may be terminated upon good cause in written form as follows:

1. On Manufacturer's part, good cause shall be acknowledged in particular in case of the following:

a) Distributor, against the stipulations of this Agreement, does not differentiate clearly between his own products and the Manufacturer's Products in his own advertising material and a term of 4 weeks has elapsed without success since he received a warning.

b) Distributor has not met his payment obligations repeatedly and a term of 2 week has elapsed without success since he received a warning.

c) Distributor will become unable to pay or, alternatively, insolvency or similar proceedings have been opened or have been rejected for the lack of assets.

d) Distributor misuses his designation as Manufacturer's distributor and a term of 1 week has elapsed without success since he received a warning.

e) Distributor becomes subject to the influence of a third party due to company law procedures and that third party is one of Manufacturer's competitors.

2. On Distributor's part, good cause shall be acknowledged in particular in case of the following:

a) Manufacturer does culpably not comply with his delivery commitment for more than 60 days, and this repeatedly, at least on 3 occasions, in spite of warning.

b) Manufacturer has culpably delivered defective Products, repeatedly, at least on 3 occasions.

c) Manufacturer has not remedied epidemic defects within 12 weeks.

d) Manufacturer will become unable to pay or, alternatively, insolvency or similar proceedings have been opened or have been rejected for the lack of assets.

**§ 15 – Termination of the Agreement**

I. Termination of this Agreement will not affect individual purchase agreements which were closed between Manufacturer and Distributor while the Agreement was still in effect. In the event of a termination with due notice, Manufacturer will continue to supply Distributor for the time which the latter needs to fulfil the purchase agreements he closed with third parties in the normal course of business before the termination became effective.

II. All documents, regardless of nature, which are Manufacturer's property shall be and remain the sole property of Manufacturer during the term of the Agreement. Any right of retention Distributor may presume regarding the said documents and papers shall be barred.

**§ 16 – Commitments on the Part of Manufacturer**

I. Manufacturer shall indemnify Distributor from all claims which may be asserted towards Distributor due to binding law – especially according to the principles of product liability – or resulting from violation of industrial property rights, if the claims are not based on negligent or intentional acts of Distributor. In the event of such claims the parties to this Agreement shall inform each other immediately. Manufacturer shall be entitled to – conduct the defence.

**§ 17 – Commitments on the Part of Distributor**

Distributor shall indemnify Manufacturer from all third party claims, especially from product liability claims, which are not related to defects of Products within Manufacturer's area of responsibility according to § 13 of this Agreement or which result from Distributor having warranted product attributes not covered by the product descriptions provided by Manufacturer.

**§ 18 – Violation of Trademark Rights**

In the event of third parties violating any existing trademark rights which underlie the Products or third parties manufacturing plagiarisms in an anticompetitive way or them illegally using identical or confusable marks, Distributor shall take action against this with all possible legal measures and to inform Manufacturer about this immediately. Distributor shall support Manufacturer in his legal action against third parties.

**§ 19 - Confidentiality**

I. Distributor shall maintain Manufacturer's business and company secrets confidential, especially Manufacturer's know-how regarding the Products which became known to Distributor during the term of the Agreement unless Distributor shall be obliged to disclose information by law. Distributor shall swear his employees to the same confidentiality as well.

II. The preceding obligations shall not apply to information for which Distributor can prove the following:

- He had knowledge of the information before he received it from Manufacturer.
- The information was public knowledge before he received it from Manufacturer.
- The information became public knowledge without him being responsible after he received it from Manufacturer.
- The information was given to him any time by a third party who, according to his best knowledge, was authorized to do so.

III. The obligations contained in this paragraph shall hold good for a term of 10 years after termination of the Agreement.

**§ 20 – Administrative Regulations**

Distributor shall be obliged to take care of any necessary registration as appointed dealer in the Territory and for compliance with any other regulations under public law for appointed dealers in the Territory.

**§ 21 – Legal Succession / Distribution Partners**

I. Distributor shall not assign rights and obligations from this Agreement to a third party without the prior specific written consent from Manufacturer. This shall also apply to company law procedures related to Distributor's legal personality, especially applicable laws regulating the transformation of companies.

II. The same shall apply to Distributor assigning sub-contracted dealers or any other distribution partners.

**§ 22 – Final Provisions**

I. No ancillary agreements have been made. This present Agreement replaces any earlier agreements between the parties.

II. The present contractual relationship shall be ruled by the Law of the United States under the exclusion of the United Nations Convention on Contracts for the International Sale of Goods (CISG).

III. Manufacturer's place of business shall be the place of jurisdiction for all differences resulting from this Agreement and from individual orders. Manufacturer shall also be entitled to sue Distributor at his place of business.

IV. Modifications or supplements to this Agreement shall be effected in written form. This shall apply as well to any waiver of the requirement for written form.

V. Should single regulations of this Agreement be or become invalid, null and void or incomplete this shall not affect the validity of the rest of the Agreement. The parties to the Agreement will replace invalid, incomplete or void clauses by supplemented or reinterpreted regulations so that the economic purpose intended with the incorrect regulation is reached.

Irvine, California

B. Schneider

for Joimax, Inc

Manufacturer

Distributor

6/24/16

**Appendix 1:** Products

**Appendix 2:** Territory

**Appendix 3:** Terms & Conditions of Trade

**APPENDIX 1: Products**

(Enclosed-current product list)

**APPENDIX 2: Territory**

Territory will be defined as the following surgeon accounts and their listed facilities. These may be amended at any time by mutual agreement and are as follows from the date of the agreement:

**UMH & Jackson Memorial**
Wang
Vanni
Levene
Manzano
Shaya
Stoev
Eismont
Brusovic
Widi

**Broward General**
Hershman
Cantor
Malloy
Hall
Cameron
Blumberg
Foltz
Goads
Casas

**Aventura Hospital**
Soto
Gonzales
Figaroa

**Hollywood North / South**
Blumberg
Cantor
Hall
Cameron

**Boca Raton Regional / Delray Medical / Delray Outpatient / Boca Outpatient**
Fernyough
Lowen
Chung
Eskenazi
Dare
Packer
Zucker
Sahai
Norton

**Martin Memorial North & South**
Szentermai
Atwater
Putney



Initials: / BDS

Prasher

**St. Lucie Medical Center**
Hrushka

**Lawnwood Medical Center**
Malloy
Atwater

**St. Mary's Medical Center / West Palm Beach Hospital**

Bach
Lenard
Roush

**Wellington Regional / JFK**

Schlifka
Cantando
Fakhoury
Dutcher
Abdolvahabi
Dare
Bach

**Jupiter Medical Center**

Biscup
Golish
Scuderi
Theofolis
Lenard
Dutcher
Roush

**Deerfield Outpatient**

Roush
Svabeck
Faderani
Appel
Zegeye

**Lake Worth Surgery Cente**
Reuter
Zegeye
Roush

**Palms West**

Abdolvahabi
Dutcher

**Midtown Surgery Center**

Dare

**Surgicare of Boca**

Bach

Porter

Barna

**APPENDIX 3: General Terms and Conditions of Trade**

Pricing as follows:

30% discount off manufacturer's list price on all Tessys capital and disposable products purchased by distributor in effect at the time of this contract. Distributor will notify joimax Inc. Of ship to address at the time of order.

35% commission off net sales price on all implant products.

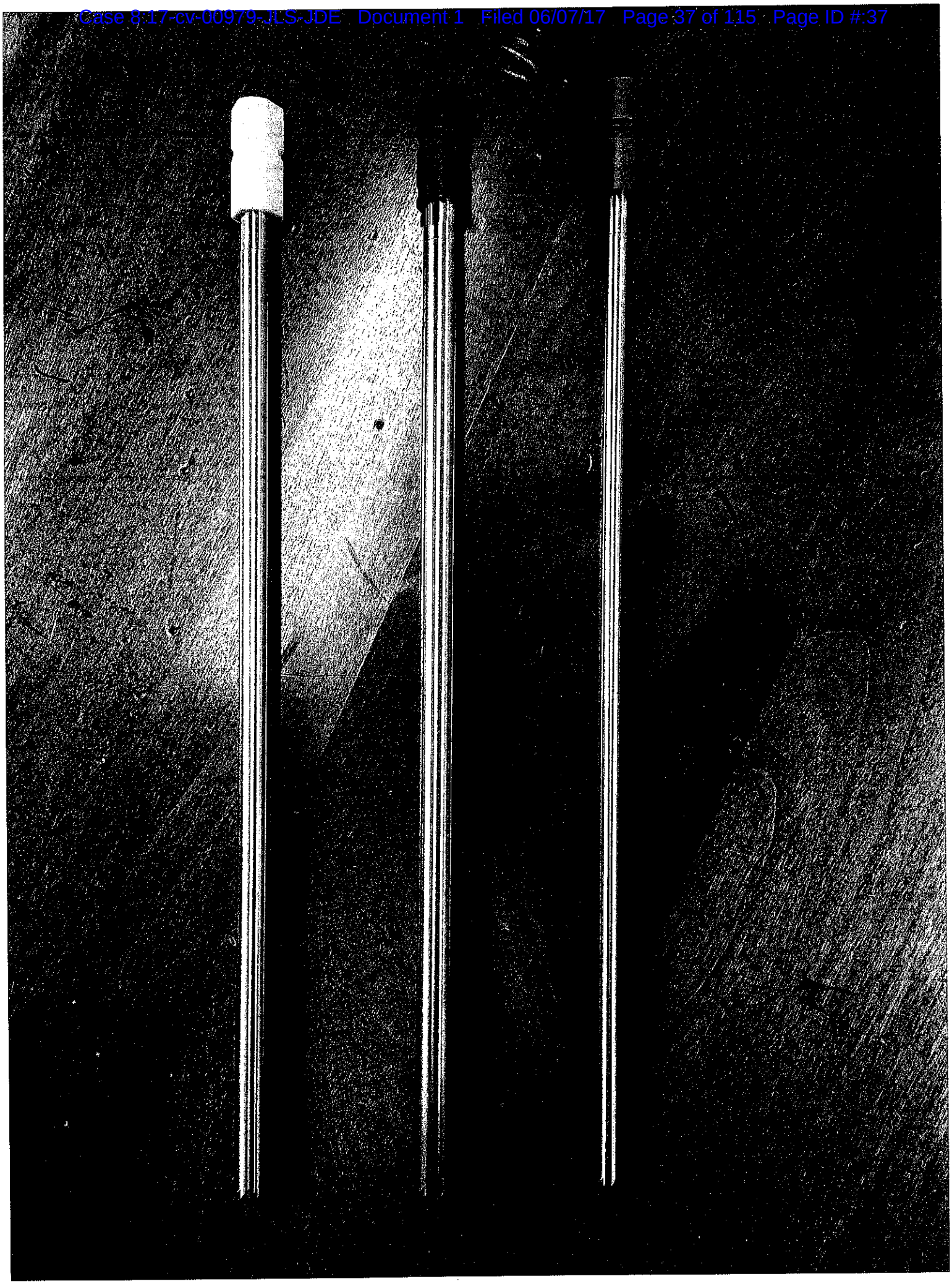
Joimax Inc. will invoice Distributor, **Surgical Orthopedic Implants, DBA, Max Spine, LLC** on net 30 day terms. Distributor will assume responsibility for invoicing their customer.

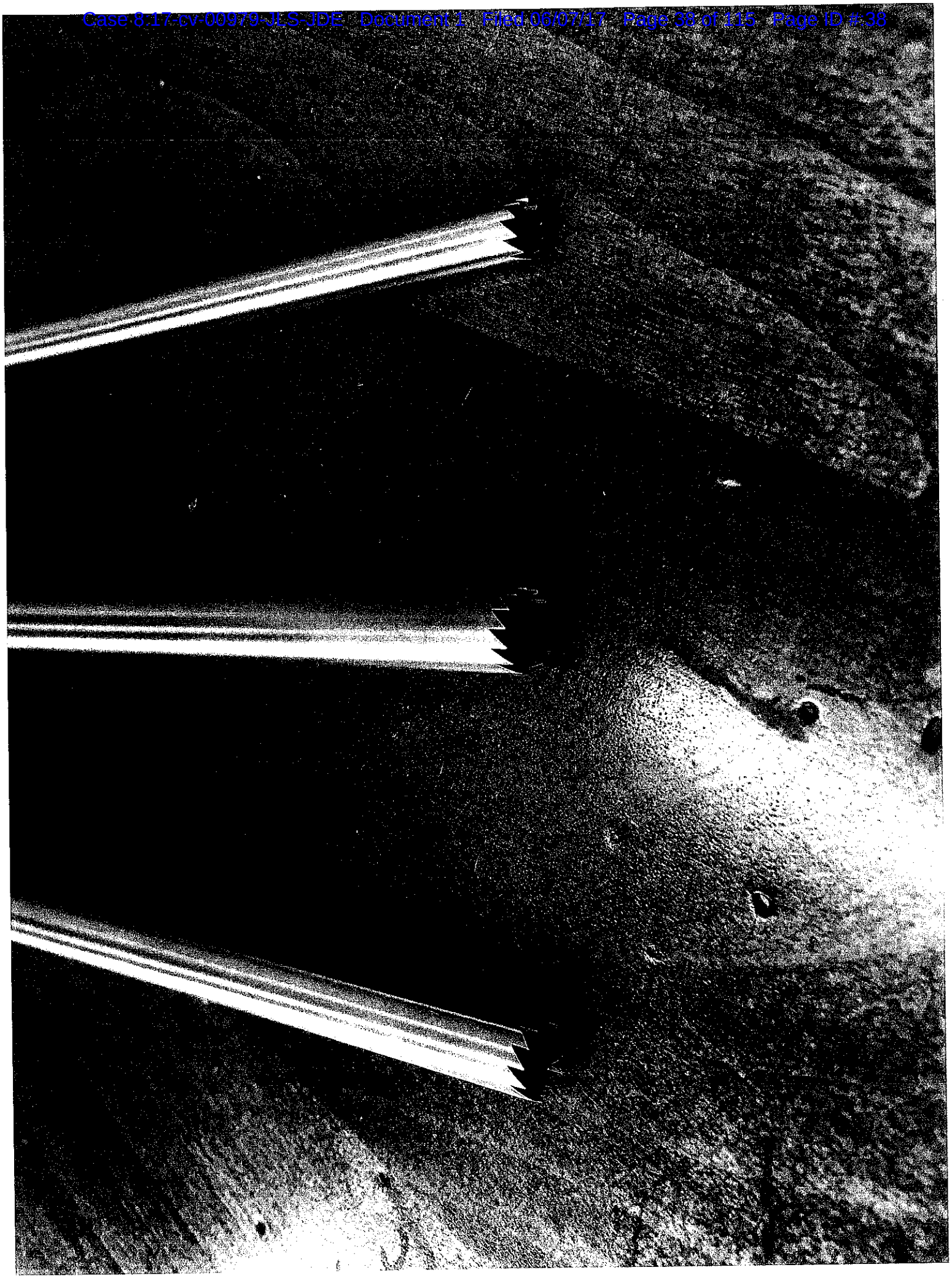
**Appendix 4** – Competitive spine hardware lines allowed

Stryker
Exactech
Titan
Choice Spine
Biocomposites
Orthomedics
Globus
Elliquence
– CAPPABIANCA BIPOLAR FORCEPS
may ALSO SUPPLY CUSTOMERS DIRECT WITH Elliquence PROD IF JOINAX UNABLE TO DO SO.

PD 6/24/16

# EXHIBIT "B"





# EXHIBIT "C"


(12) **United States Patent**
**Ries et al.**

(10) **Patent No.: US 8,267,937 B2**
(45) **Date of Patent: Sep. 18, 2012**

(54) **METHOD FOR DETERMINING A TOOTH PERIOD LENGTH OF A BONE MILLING CUTTER**

(75) Inventors: **Wolfgang Ries**, Linkenheim (DE); **Mathias Notheis**, Forst (DE)

(73) Assignee: **Joimax GmbH**, Karlshure (DE)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1407 days.

(21) Appl. No.: **11/898,231**

(22) Filed: **Sep. 11, 2007**

(65) **Prior Publication Data**

US 2008/0077148 A1 Mar. 27, 2008

(30) **Foreign Application Priority Data**

Sep. 27, 2006 (DE) ..... 10 2006 045 508

(51) **Int. Cl.**
***A61B 17/00*** (2006.01)

(52) **U.S. Cl.** ..... **606/79**; 606/80; 76/115

(58) **Field of Classification Search** ..... 606/80; 29/407.01, 407.05; 76/115
See application file for complete search history.

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| 2006/0008771 | A1 | 1/2006 | Courvolsier | |

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| | | |
|---|---|---|
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| DE | 202005016762 | 1/2007 |
| DE | 202005016763 | 1/2007 |
| EP | 0 296 986 | 12/1988 |

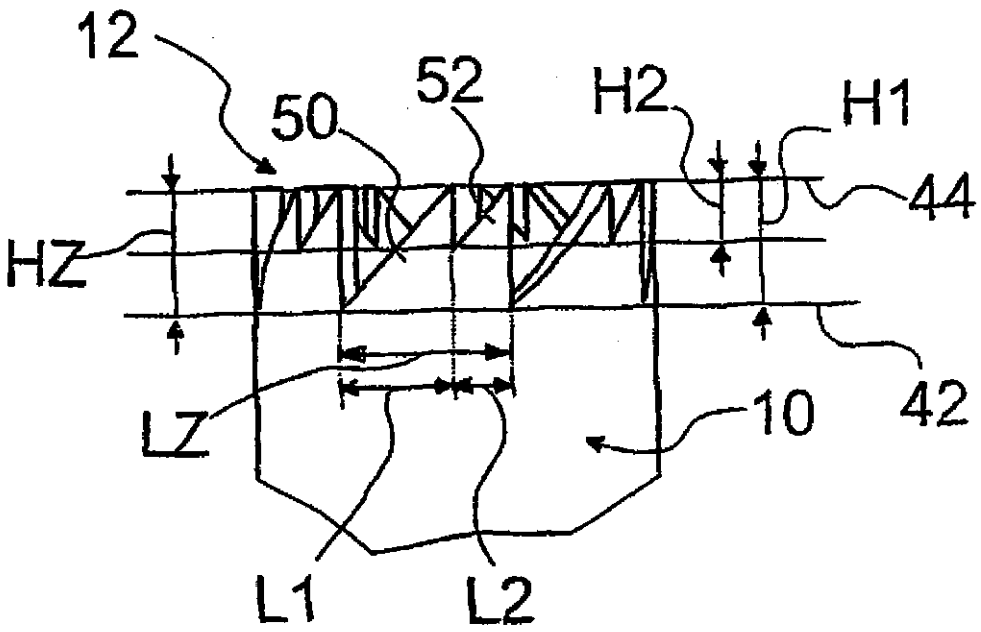
* cited by examiner

*Primary Examiner* — Andrew Yang
(74) *Attorney, Agent, or Firm* — McGlew and Tuttle, P.C.

(57) **ABSTRACT**

A method for manufacturing bone milling cutters, wherein a milling cutter toothing (**12**) is created at a distal face of a tubular milling cutter shaft (**10**) of a bone milling cutter at a given outer diameter (D) of the milling cutter shaft (**10**). The following steps are carried out: determining the tube circumference (U) of the milling cutter shaft (**10**); ascertaining an average desired tooth height (Hgew) of the milling cutter toothing (**12**); ascertaining the desired tooth period length (LZ') of the milling cutter toothing from the desired tooth height (Hgew) at given parameters of a tooth period pattern; dividing the tube circumference (U) by the desired tooth period length (LZ); rounding the results to an even number value (Qz); and dividing the tube circumference (U) by the value (Qz) in order to obtain the tooth period length (LZ).

**20 Claims, 4 Drawing Sheets**



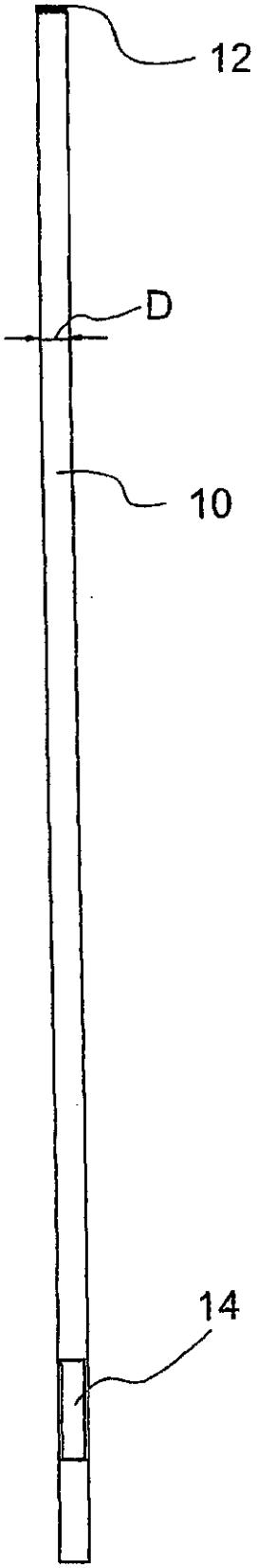



Fig. 1

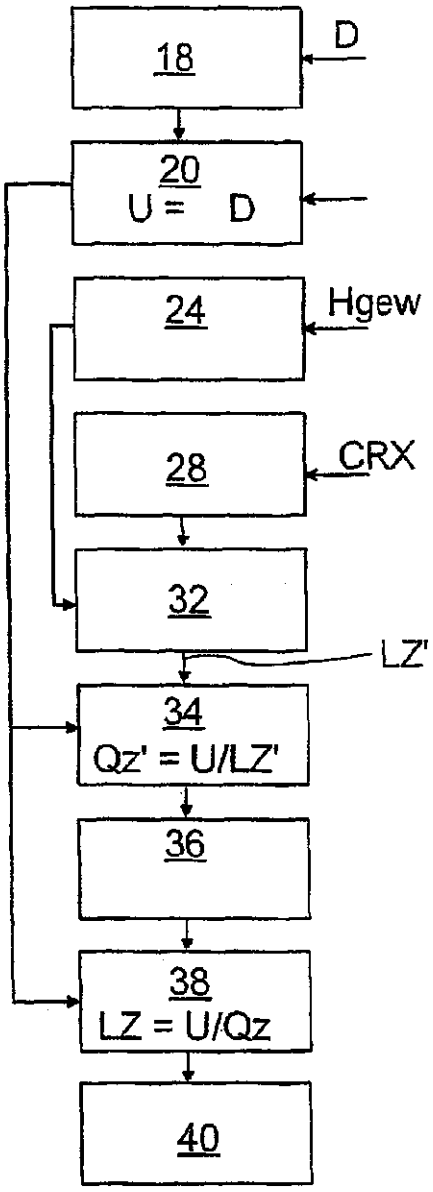

18
D
20
U = D
24
Hgew
28
CRX
32
LZ'
34
Qz' = U/LZ'
36
38
LZ = U/Qz
40

Fig. 2

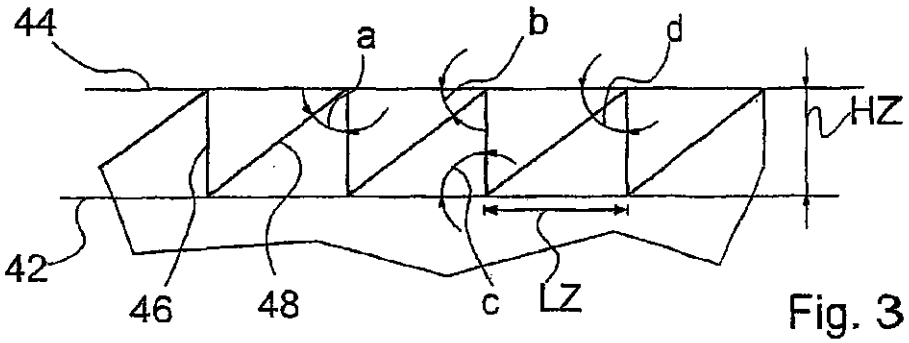

44
a
b
d
HZ
42
46
48
c
LZ

Fig. 3

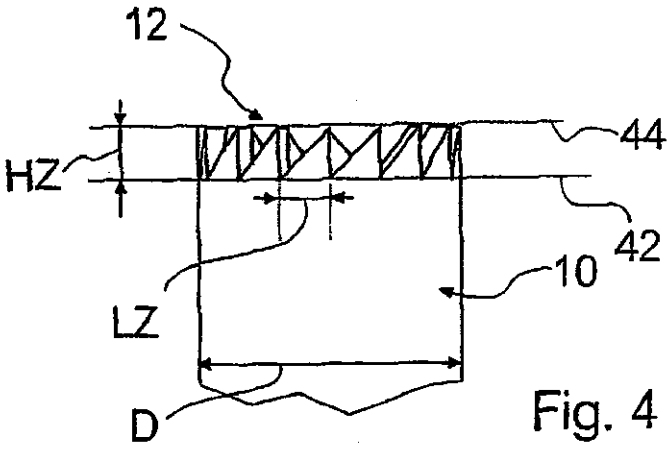



Fig. 4

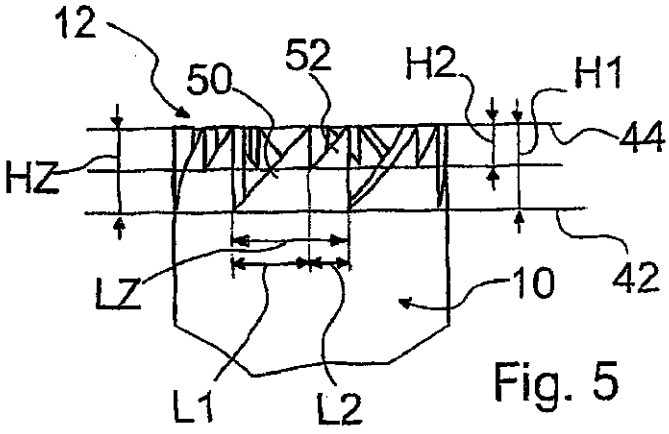



Fig. 5

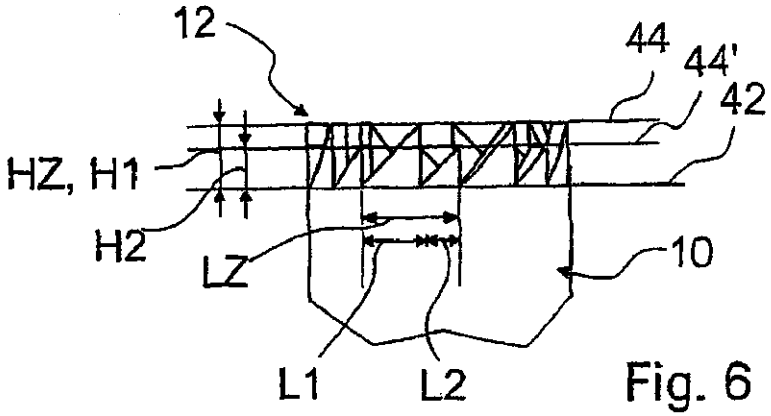



Fig. 6

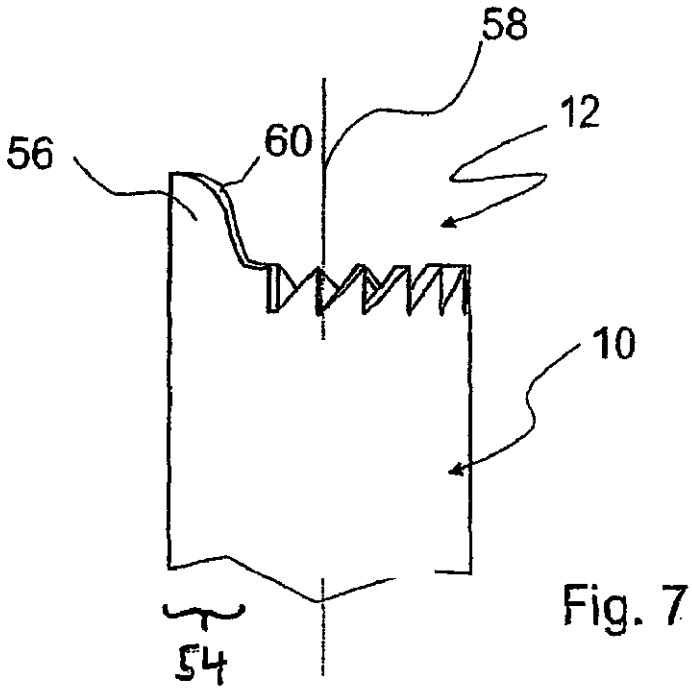



Fig. 7

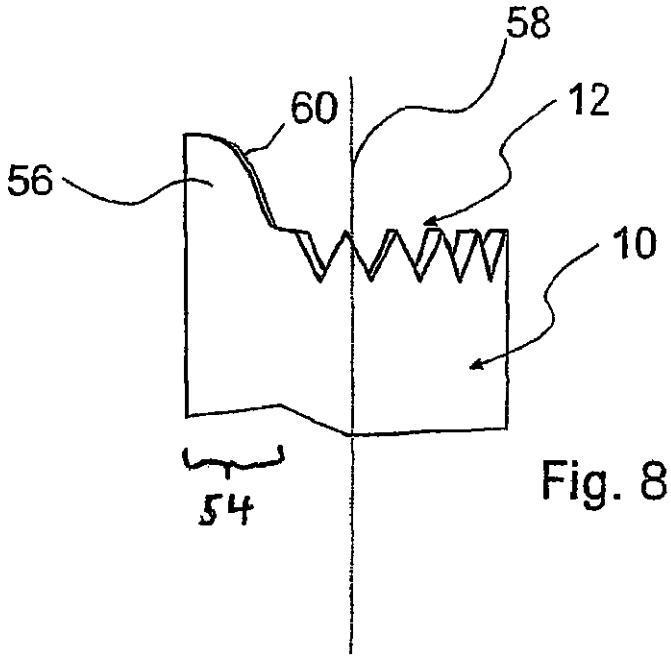



Fig. 8

# METHOD FOR DETERMINING A TOOTH PERIOD LENGTH OF A BONE MILLING CUTTER

This application claims Paris Convention priority of DE 10 2006 045 508.8 filed Sep. 27, 2006 the complete disclosure of which is hereby incorporated by reference.

## BACKGROUND OF THE INVENTION

The invention relates to a method for manufacturing bone milling cutters, wherein a milling cutter toothing is created at a distal face of a tubular milling cutter shaft of a bone milling cutter at a given outer diameter of the milling cutter shaft as well as to a device for manufacturing bone milling cutters with which a milling cutter toothing is created at a digital face of a tubular milling cutter shaft of a tubular milling cutter shaft of a bone milling cutter at a given outer diameter of the milling cutter shaft. The invention further relates to a bone milling cutter with a tubular milling cutter shaft and a milling cutter toothing at a distal face of the tubular milling cutter shaft, wherein the milling cutter toothing is formed from a number of tooth period patterns periodically distributed over at least a part of a tube circumference of the milling cutter shaft.

A conventional a bone milling cutter, for example from DE 699 17 683 T2, has a hollow cylindrical milling cutter shaft, a handle at its rear, proximal end and a milling cutter toothing at its front or distal end.

Such a milling cutter is employed in the field of medical technology to mill out vertebra components in the area of a lateral process of a spine vertebra in order to establish postero-lateral access to pinched nerve roots of the central nervous system. Nucleus propulsus tissue and other tissue types (capsule tissue, scar tissue, annulus tissue) are then removed through this access because they press on the nerve roots. The specified process of a vertebra forms, together with an adjacent process of an adjacent vertebra, the so-called facet joint.

The micro invasive operation method, which employs a generic facet joint milling cutter and which is for decompressing pinched nerve roots, is highly successful. Due to the high sensitivity of such an intervention, generic bone milling cutters must be made in an extremely precise manner and must have a high degree of toughness in order to avoid blunting of the toothing. Furthermore, such a bone-milling cutter must be stable during use and must not slip under any circumstances. All of these requirements must be fulfilled with the ability to disinfect both simply and well. For this reason, the manufacture of bone milling cutters of the generic type, which is additionally carried out in small numbers, is very expensive. In particular, this is important because a surgeon generally does not need only one bone milling cutter, but rather a whole range with various dimensions and toothing patterns.

Departing from this prior art, the invention has the objective of creating a method for manufacturing a bone-milling cutter in which the manufacturing cost is reduced compared to milling cutter toothings, which are dimensioned in accordance with the known method while avoiding the stated disadvantages. Moreover, the method should facilitate dimensioning of a milling cutter such that good stability and toughness of the toothing is ensured during use of the bone-milling cutter.

## SUMMARY OF THE INVENTION

According to the invention, the object is achieved with a method of the generic type, which is characterized by the following steps:



determining the tube circumference of the milling cutter shaft;

ascertaining an average desired tooth height of the milling cutter toothing;

ascertaining the desired tooth period length of the milling cutter toothing from the desired tooth height at given parameters of a tooth period pattern;

dividing the tube circumference by the desired tooth period length;

rounding the results to an even number value;

dividing the tube circumference by the value in order to obtain the tooth period length.

The method according to the invention can be particularly advantageously implemented in a device for manufacturing a bone milling cutter which is configured in accordance with the invention and in which the dimensioning of bone milling cutters, made individually or in small production runs, can be calculated automatically using the method according to the invention depending on few parameters, for example the tooth height, and can flow directly into the manufacturing process.

Finally, the object of the invention is solved by a bone milling cutter in which the number of the tooth period patterns is an even number and/or in which at least one pair of tooth period patterns is arranged point-symmetrically with regard to a center line of the tubular milling cutter shaft.

By selecting an even-number value for the number of the tooth period patterns distributed over the tube circumference, there can be achieved, in particular in the case of a simple tooth period pattern, in a particularly simple manner, a paired point-symmetrical arrangement of the tooth period patterns which strongly simplifies manufacture and thereby makes it less expensive. Opposing tooth period patterns can be processed simultaneously, while guaranteeing a radial course of cutting edges.

Herein, "length" refers to the extension of the tooth period pattern or of an individual tooth in the circumference direction of the milling cutter shaft, while the term "height" refers to the axial direction of the milling cutter shaft.

Instead of directly involving the circumference of the tube, the outer diameter of the tube can be specified as a parameter, with the tube circumference then being determined from the outer diameter of the milling cutter shaft. For example, a radius can be specified instead of the outer diameter. The outer diameter or a parameter that is proportional thereto can, for example, be read in and set from a database or by a user interface.

Ascertaining an average desired tooth height of the milling cutter toothing can also be carried out by reading-in from a database or using a user interface.

According to a particularly advantageous embodiment of the method according to the invention, an adaptation, in particular a scaling of the tooth height or an adaptation of the wedge angle and/or angle of incidence of the tooth period pattern can, after ascertaining the tooth period length, be carried out in order to set the ascertained tooth period length in an advantageous proportion to the tooth height. Thus, in certain circumstances, small deviations of the ultimate tooth height from the desired tooth height, as well as deviations of the ultimate ascertained tooth shape from the desired tooth shape, as determined by the given parameters of the tooth period pattern, can be tolerated.

A possible design of the above-defined device according to the invention allows for the parameters for the tooth period pattern to comprise at least one wedge angle and/or one angle of incidence. As both the cutting characteristics and the height/length ratios of a saw tooth are largely determined by these angles, they form particularly significant parameters.

If the tooth period pattern contains at least one pair of teeth, wherein a fraction of the tooth period length is advantageously formed in order to determine the length of at least one tooth of the tooth period pattern and/or wherein, in particular, a fraction of the tooth height is formed in order to determine the height of at least one tooth of the tooth period pattern, the method according to the invention can be generalized simply from individual teeth to more complex teeth period patterns.

If the height of the larger tooth and the height of the smaller tooth are determined starting from a common tooth tip line, substantial stability of the larger teeth can be achieved with highly effective material removal. Therefore, bone-milling cutters of this type with medium-sized double teeth are particularly suitable for precise work with good tooth stability and good removal of material.

A disadvantageous alteration of the length relationship between the smaller tooth and the larger tooth can be avoided if the length of at least one larger and one smaller tooth of the tooth period pattern is determined such that the proportions do not move due to the variation in length of an individual tooth.

A bone milling cutter which is particularly well dimensioned for precise working with good teeth stability and good material removal can be achieved by the method according to the invention if, when ascertaining the desired tooth period length from the tooth height of the milling cutter toothing, the length of the larger tooth of the tooth period pattern is determined such that it is ⅔ of the tooth height, with the length of the smaller tooth of the tooth period pattern being determined such that it is ⅓ of the tooth height, wherein the tooth period length corresponds to the sum of the lengths of the teeth.

In order to achieve a bone milling cutter, in particular one with rough toothing, which is particularly suitable for the largest degree of effectiveness in removing material with good teeth stability, it is proposed that the height of the larger tooth and the height of the smaller tooth be determined starting from a common tooth base line. The effectiveness in the case of material removal arises from the fact that, as a result of this dimensioning, the smaller teeth remain hidden below the tooth tip line of the larger teeth.

Surprisingly, it was discovered that the effectiveness in the case of high stability is particularly high if, when ascertaining the desired tooth period length from the tooth height of the milling cutter toothing, the length of the larger tooth of the tooth period pattern is determined such that it is ⅗ of the tooth height and that the length of the smaller tooth of the tooth period pattern is determined such that it is ⅖ of the tooth height, wherein the tooth period length corresponds to the sum of the lengths of the teeth.

The milling cutter is normally made of stainless steel. Preferably, the toothing is configured in that the toothing is configured at the distal tube end by means of mechanical removing or severing of material, with the toothing in particular being created by laser welding. Alternatively, other methods such as grinding, milling or etching can be employed.

Further advantages and features of the invention arise from the claims and from the subsequent description in which embodiments of the invention are explained in detail. In the figures:

## BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** shows a bone-milling cutter with a milling cutter toothing;

FIG. **2** shows a flow chart of a method for determining a tooth period length of a milling cutter toothing;



FIG. **3** shows a detail from a milling cutter toothing for illustrating parameters of the tooth period pattern;

FIG. **4** shows a distal end of a bone-milling cutter with a milling cutter toothing of a CRF toothing type;

FIG. **5** shows a distal end of a bone-milling cutter with a milling cutter toothing of a CRM toothing type;

FIG. **6** shows a distal end of a bone-milling cutter with a milling cutter toothing of a CRC toothing type;

FIG. **7** shows a distal end of a bone milling cutter with a milling cutter toothing of a CRP toothing type; and

FIG. **8** shows a distal end of a bone-milling cutter with a milling cutter toothing of a CRPF toothing type.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** shows a bone milling cutter which has a hollow cylindrical milling cutter shaft **10**, a handle, which is not depicted here, at its rear proximal end and a milling cutter toothing **12** of a first type at its front or distal end. The milling cutter shaft **10** has, at its proximal end, a recess **14** for fixing the handle.

Such a bone-milling cutter is employed in the field of medical technology to mill out vertebra components in the area of a lateral process of a spine vertebra in order to establish a postero-lateral access to pinched nerve roots of the central nervous system.

The bone milling cutter depicted in FIG. **1** is the direct product of a manufacturing method which, alongside known processing steps, in which, in the case of known sizes of bone milling cutters, this is made from a metal tube, comprises a method for determining the dimensions of the bone milling cutter, as is depicted in FIG. **2**. In the latter method, there is determined in particular a tooth period length LZ of a milling cutter toothing **12** at a distal face of a tubular milling cutter shaft **10** of the bone milling cutter, in the case of a given outer diameter D of the milling cutter shaft **10**.

The method steps illustrated in FIG. **2** are thereby carried out.

In a first step **18**, the outer diameter D from a calculation unit which is not depicted here and which controls the method is read in from a database or a user interface.

In a first calculating step **20**, the calculation unit calculates the tube circumference U from the outer diameter D of the milling cutter shaft **10** by multiplying the outer diameter D by the number 0 which it reads in from read-only memory.

Subsequently, the calculation unit ascertains, in a step **24**, an average desired tooth height Hgew of the milling cutter toothing **12** by reading in this value, which is supplied by an operator.

Furthermore, the calculation unit ascertains in a toothing type ascertaining step **28** with which of **5** different toothing types CRX. CRX refers to a variable, which codes the toothing type with which the bone-milling cutter to be produced should be equipped. The variable CRX can assume values CRX=CRF, CRM, CRC, CRP or CRPF. The toothing types CRX are explained further below (FIGS. **4-8**).

Subsequently, the calculation unit ascertains a target value for the tooth period length LZ' in a length determination step **32** from the desired tooth height Hgew ascertained in the step and depending on the toothing type CRX which is coded by given parameters of a tooth period pattern.

In a dividing step **34**, the calculating unit divides the tube circumference U by the desired tooth period length LZ' or the target value and, in a rounding step **36**, rounds the result to an even-number value Qz.

Finally, in a second dividing step **38**, the calculating unit divides the tube circumference U by the value Qz in order to obtain the tooth period length LZ.

After ascertaining the tooth period length LZ, a scaling of the actual tooth height H takes place in an adaptation step **40** through the ratio consisting of the desired tooth period length LZ' and the actual tooth period length LZ obtained in the second dividing step **38**. By means of the scaling, it is achieved that the wedge angle a and/or angle of incidence c of the tooth period pattern are independent from the desired tooth height Hgew.

By selecting an even-number value Qz for the number of the tooth period patterns distributed over the tube circumference U, a paired point-symmetrical arrangement of the individual tooth period patterns is achieved in a particularly simple manner which greatly simplifies manufacture and therefore makes it less expensive. Opposing tooth period patterns can be processed simultaneously, wherein a radial course of cutting edges can be guaranteed.

In advantageous embodiments, there arise for the value Qz even numbers between 6 and 30 in the case of outer diameters D between 2 and 9.5 mm.

The parameters for the tooth period pattern comprise, for example, a wedge angle a and/or an angle of incidence c. Therefore, in the length determination step **32**, the tooth length or tooth period length LZ can be determined by simple trigonometric calculations, since the projection of the tooth flanks on the circumference direction of the milling cutter shaft **10** can be calculated simply by multiplying the desired tooth height Hgew by the inverse cosine of the corresponding angle. Of course, instead of the angles, it is also possible to directly store the inverse cosine or another suitable trigonometric function as a parameter.

FIGS. **3-8** show concrete embodiments with different tooth period patterns. The subsequent description is limited to those differences in the method for determining the tooth period length LZ which arise from the different tooth period patterns, while, in view of the constant features, reference is made to the above general description of the method.

A device according to the invention is configured for carrying out the thus-specified steps and for creating the suitable toothing at a shaft.

FIG. **3** shows a detail from a milling cutter toothing **12** with a simple tooth period pattern of the type **30**=CRF with only one tooth. The tooth has a wedge angle a of 45° and an angle of incidence c of 90°. The distal end, which is depicted in FIG. **4**, of a bone-milling cutter is equipped with the milling cutter toothing **12**, which is depicted in FIG. **3**. This is particularly suitable for fine works shortly before the end of the operation where efficiency in terms of material removal is of lesser importance compared to the required precision.

In the example from FIGS. **3** and **4**, the length determination step **32** turns out to be particularly simple because, due to the wedge angle s of 45°, the tooth period length LZ is identical to the desired tooth height Hgew, such that the two values can simply be equalized. For the toothing type CRX=CRF, the intersecting angle is d=90° and the clearance angle is b=45°.

In general, the parameters of the tooth period pattern are angles between a pair of characteristic straight lines of the tooth period pattern. The characteristic straight lines are, in particular, the tooth base line **42**, the tooth tip line **44**, the cutting tooth face **46** and the tooth back **48**, wherein, in the case of several teeth in a tooth period pattern, different angles can also be assigned to the cutting tooth faces **46** and the tooth backs **48**. The interior angle between the cutting tooth face **46** and the tooth back **48** is also referred to as wedge angle a, the interior angle between the tooth base line **42** and the cutting tooth face **46** is referred to as angle of incidence c, the angle between the tooth back **48** and the tooth tip line **44** is referred to as clearance angle b and the angle between the tooth tip line **44** and the cutting tooth face **46** is referred to as intersecting angle d.

If the tooth period pattern contains at least one pair of teeth, as is the case with toothing types depicted in FIGS. **5** and **6**, the calculation unit forms, in the length determination step **32**, a fraction of the desired tooth height Hgew in order to determine the height and length of at least one tooth of the tooth period pattern.

In the embodiment depicted in FIG. **5** of the toothing type CRX=CRM, the length L1 of the larger tooth **50** of the tooth period pattern is determined in length determination step **32**, when ascertaining the desired tooth period length LZ from the desired tooth height Hgew of the milling cutter toothing **12**, such that it is ⅔ of the tooth height Hgew and the length L2 of the smaller tooth **52** of the tooth period pattern is determined such that it is ⅓ of the tooth height Hgew. The wedge angle a of the teeth **50**, **52** is 45° and the angle of incidence c is 90°. The toothing type CRX=CRM is designed for precise work with a large degree of stability of the teeth **50**, **52** and good removal of the material. In the length determining step **32**, both the length L2 of the smaller tooth **52** and the length L1 of the larger tooth **50** is determined proportional to the desired tooth height Hgew such that the proportions are set independently of the desired tooth height Hgew, wherein the tooth period length LZ always corresponds to the sum of the lengths L**1**, L**2** of the teeth **50**, **52**.

The vertical arrangement of the two teeth **50**, **52** of the tooth period pattern of the CRM type is chosen such that the height HI of the larger tooth **50** and the height H2 of the smaller tooth **52** are determined starting from a common tooth tip line **44**. Bone milling cutters of this type with medium-sized double teeth are thus particularly suitable for precise working with good stability of the teeth **50**, **52** and good removal of material.

In advantageous embodiments of bone milling cutters with tooth period patterns of the CRM type, there arise for the value Qz numbers between 2 and 9 in the case of outer diameters D between 2 and 9.5 mm. The length of the small tooth **52** is then between 1.0472 mm and 1.1054 mm and the length of the larger tooth **50** is then between 2.0944 mm and 2.2108 mm.

A bone milling cutter, which is particularly well dimensioned for a high degree of material removal, is achieved by means of the toothing type CRX=CRC which is depicted in FIG. **6**. Bone milling cutters with the toothing type CRX=CRC are particularly suitable for rough preliminary work in which a larger amount of material needs to be removed and in which precision is of secondary importance. In the length determination step **32**, when ascertaining the desired tooth period length LZ from the tooth height Hgew of the milling cutter toothing **12**, length L1 of the larger tooth **50** of the tooth period pattern is determined such that it is ⅗ of the desired tooth height Hgew and such that the length L2 of the smaller tooth **52** of the tooth period pattern is determined such that it is ⅖ of the tooth height Hgew, wherein the tooth period length LZ corresponds to the sum of the lengths L**1**, L**2** of the teeth **50**, **52**.

In a bone milling cutter of the toothing type CRX=CRC, the height H1 of the larger tooth **50** and the height H2 of the smaller tooth **52** is determined starting from a common tooth base line **42** such that the tooth tip line **44'** of the smaller teeth **52** is situated under the tooth tip line **44** of the larger teeth **50**. The effectiveness in terms of material removal arises from the

fact that, as a result of this dimensioning, the smaller teeth **52** remain hidden below the tooth tip line **44** of the larger teeth **50**.

FIG. **7** shows a bone milling cutter with a milling cutter toothing **12** of the tooth type CRX=CRP. This toothing type is characterized in that the milling cutter toothing **12** does not extend over the entire circumference of the face of the milling cutter shaft **10** but rather discontinues in a sector **54** in which there is provided a protector lip **56** which axially protrudes over the milling cutter toothing **12**. The protector lip **56** extends over an angle area which can, in principle, be freely selected but is normally situated between 90° and 180° such that, in any case, a pair of tooth periods is point-symmetrical with regard to the center line **58** of the tubular milling cutter shaft **10**. The point-symmetry relates to the axial plan view.

Such a bone-milling cutter can be employed to protect tissue arranged beside the bone to be processed and to avoid injuries. Besides, the milling cutter toothing **12** in the bone-milling cutter depicted in FIG. **7** matches that of toothing type CRM.

FIG. **8** shows a bone milling cutter with a milling cutter toothing **12** of the toothing type CRX=CRPF. Like the toothing type CRX=CRP, this toothing type has a protector lip with a front rasp **60**. However, the toothing in the area of the distal front, which completes the protector lip into a circle, corresponds to a toothing type with isosceles teeth for working on impact.

Independent of the selection of the toothing type CRX, the result of the above-described manufacturing method is a bone milling cutter with a tubular milling cutter shaft **10** and a milling cutter toothing **12** at a distal face of the tubular milling cutter shaft **10**, wherein the milling cutter toothing **12** is formed by a number of tooth period patterns periodically distributed over at least a part of a tube circumference U of the milling cutter shaft **10**. The characteristic of the bone milling cutter is that at least a pair of tooth period patterns is arranged point-symmetrically with regard to a center line **58** of the tubular milling cutter shaft **10** because the number Uzi of tooth period patterns is an even number.

As is also the case for the toothing type CRX=CRF, the intersecting angle d is 90° and the clearance angle b is 45° in the toothing types CRM, CRC, CRP and CRPF. In order to generalize the method according to the invention to other toothing types in which the angle of incidence c deviates from 90°, the tooth lengths can be ascertained in the length determination step **32** simply by the desired tooth height Hgew and using the trigonometric functions. Toothing types, with which it is possible to work on impact (angle of incidence c<90°) or on pulling (angle of incidence c>90°), can thus also be achieved.

The above-described methods may obviously also be employed for dimensioning further tooth period patterns which appear sensible to the person skilled in the art, for example for those with a curved cutting tooth face or for those with more than two teeth. Furthermore, the methods are not limited to bone milling cutters with a purely cylindrical milling cutter shaft **10** but may also be employed in conjunction with milling cutter shafts which expand radially in the area of the milling cutter toothing **12** or below the milling cutter toothing **12**.

LIST OF REFERENCE NUMERALS

**10** milling cutter shaft
**12** milling cutter toothing
**14** recess
**18** step
**20** calculating step
**24** step
**28** toothing type ascertaining step
**32** length determination step
**34** dividing step
**36** rounding step
**38** dividing step
**40** adapting step
**42** tooth base line
**44** tooth tip line
**46** cutting tooth face
**48** tooth back
**50** tooth
**52** tooth
**54** sector
**56** protector lip
**58** center line
**60** rasp
a wedge angle
b clearance angle
c angle of incidence
d intersecting angle
L1 length
L2 length
H1 height
H2 height
Hgew, HZ tooth height
LZ, LZ' tooth period length
U tube circumference
D outer diameter
Qz value
CRX toothing type

We claim:

**1**. A method for manufacturing a bone milling cutter, the method comprising:

providing a tubular milling cutter shaft;

determining a tube circumference of the milling cutter shaft;

determining an average desired tooth height of the milling cutter toothing after determining said tube circumference of the milling cutter shaft;

determining a desired tooth period length of the milling cutter toothing from the desired tooth height at given parameters for a tooth period pattern after determining said average desired tooth height of said milling cutter toothing;

dividing the tube circumference by the desired tooth period length to form a divided result and rounding said divided result to an even number value after determining said desired tooth period length of the milling cutter toothing;

dividing the tube circumference by the even number value after dividing the tube circumference by the desired tooth period length to obtain an actual tooth period length; and

mechanically removing or severing material to form a plurality of teeth at a distal end of the milling cutter shaft via one of laser cutting, grinding, milling and etching based on said actual tooth period length after obtaining said actual tooth period length, each of said teeth comprising said desired tooth period length of said milling cutter toothing.

**2**. The method of claim **1**, wherein a height of a larger tooth and a height of a smaller tooth are determined starting from a common tooth base line.

**3**. A method in accordance with claim **1**, wherein a height of at least one larger and one smaller tooth of the tooth period

pattern is determined, wherein the height of the larger tooth and the height of the smaller tooth are determined starting from a common tooth tip line.

4. A method in accordance with claim 1, wherein a protector lip extends in a circumferential direction at said distal end of said milling cutter shaft, said protector lip extending between one of said plurality of teeth and another one of said plurality of teeth, said protector lip extending in an axial direction of said milling cutter shaft, said protector lip having an end portion, said end portion being located at a spaced location from each of said plurality of teeth in said axial direction.

5. A method of claim 1, wherein, when determining the desired tooth period length from the desired tooth height of the milling cutter toothing, a length of the larger tooth of the tooth period pattern is determined such that the length of the larger tooth is ⅔ of a tooth height and a length of the smaller tooth of the tooth period pattern is determined such that the length of the smaller tooth is ⅓ of a tooth height, wherein the tooth period length corresponds to a sum of lengths of the teeth.

6. A method for manufacturing a bone milling cutter, the method comprising:

providing a cutting device;

providing a tubular milling cutter shaft;

determining a tube circumference of the milling cutter shaft;

determining an average desired tooth height of the milling cutter toothing after determining said tube circumference of the milling cutter shaft;

determining a desired tooth period length of the milling cutter toothing from the desired tooth height at given parameters for a tooth period pattern after determining said average desired tooth height of said milling cutter toothing;

dividing the tube circumference by the desired tooth period length to provide a quotient and rounding said quotient to an even number value after determining said desired tooth period length of the milling cutter toothing;

dividing the tube circumference by the even number value to obtain an actual tooth period length after dividing the tube circumference by the desired tooth period length; and

forming a plurality of teeth at a distal end of said milling cutter shaft by cutting material at said distal end of said milling cutter shaft with said cutting device based on said actual tooth period length after obtaining said actual tooth period length.

7. A method in accordance with claim 6, wherein said cutting includes one of laser cutting, milling, grinding and etching.

8. A method in accordance with claim 6, wherein a height of at least one larger and one smaller tooth of the tooth period pattern is determined, wherein the height of the larger tooth and the height of the smaller tooth are determined starting from a common tooth tip line.

9. A method in accordance with claim 6, wherein a protector lip extends in a circumferential direction at said distal end of said milling cutter shaft, said protector lip extending between one of said plurality of teeth and another one of said plurality of teeth, said protector lip extending in an axial direction of said milling cutter shaft, said protector lip having an end portion, said end portion being located at a spaced location from each of said plurality of teeth in said axial direction.

10. A method of claim 6, wherein, when determining the desired tooth period length from the desired tooth height of the milling cutter toothing, a length of the larger tooth of the tooth period pattern is determined such that the length of the larger tooth is ⅔ of a tooth height and a length of the smaller tooth of the tooth period pattern is determined such that the length of the smaller tooth is ⅓ of a tooth height, wherein the tooth period length corresponds to a sum of lengths of the teeth.

11. A method for manufacturing a bone milling cutter, wherein a milling cutter toothing is created at a distal face of a tubular milling cutter shaft of a bone milling cutter and at a given outer diameter of a milling cutter shaft, the method comprising the following steps, executed in sequence:

a) determining a tube circumference of the milling cutter shaft;

b) ascertaining an average desired tooth height of the milling cutter toothing;

c) ascertaining a desired tooth period length of the milling cutter toothing from the desired tooth height at given parameters for a tooth period pattern;

d) dividing the tube circumference by the desired tooth period length and rounding the results to an even number value;

e) dividing the tube circumference by the even number value to obtain an actual tooth period length; and

f) mechanically removing or severing material at the distal end of the milling cutter shaft to configure previously determined milling cutter toothing via one of laser cutting, grinding, milling and etching, said tooth period pattern containing at least one pair of teeth, wherein a height of at least one larger and one smaller tooth of the tooth period pattern is determined, wherein the height of the larger tooth and the height of the smaller tooth are determined starting from a common tooth tip line.

12. The method of claim 11, wherein the tube circumference is determined by an outer diameter.

13. The method of claim 11, wherein the parameters for the tooth period pattern comprise at least one wedge angle.

14. The method of claim 11, wherein the parameters for the tooth period pattern comprise at least one angle of incidence.

15. The method of claim 11, wherein a fraction of the tooth period length is formed to determine a length of at least one tooth of the tooth period pattern.

16. The method of claim 11, wherein a fraction of the tooth height is formed to determine a height of at least one tooth of the tooth period pattern.

17. The method of claim 11, wherein a length of the at least one larger and one smaller tooth of the tooth period pattern is determined.

18. The method of claim 17, wherein, when ascertaining the desired tooth period length from the desired tooth height of the milling cutter toothing, a length of the larger tooth of the tooth period pattern is determined such that the length of the larger tooth is ⅔ of a tooth height and a length of the smaller tooth of the tooth period pattern is determined such that the length of the smaller tooth is ⅓ of a tooth height, wherein the tooth period length corresponds to a sum of lengths of the teeth.

19. The method of claim 11, wherein, when ascertaining the desired tooth period length from the tooth height of the milling cutter toothing, a length of the larger tooth of the tooth period pattern is determined such that the length of the larger tooth is ⅗ of the desired tooth height and a length of the smaller tooth of the tooth period pattern is determined such that the length of the smaller tooth is ⅖ of the tooth height, wherein the tooth period length corresponds to a sum of the lengths of the teeth.

20. A method in accordance with claim 11, wherein said distal end of said milling cutter shaft comprises a plurality of teeth and a protector lip extending in a circumferential direction at said distal end of said milling cutter shaft, said protector lip extending between one of said plurality of teeth and another one of said plurality of teeth, said protector lip



extending in an axial direction of said milling cutter shaft, said protector lip having an end portion, said end portion being located at a spaced location, in said axial direction, from each of said plurality of teeth.

* * * * *

# EXHIBIT "D"

US008449546B2

(12) **United States Patent**
**Ries**

(10) **Patent No.: US 8,449,546 B2**
(45) **Date of Patent: May 28, 2013**

(54) **SPINE CUTTER**

(75) Inventor: **Wolfgang Ries**, Linkenheim (DE)

(73) Assignee: **Joimax GmbH**, Karlsruhe (DE)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 375 days.

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(51) **Int. Cl.**
***A61B 17/16*** (2006.01)

(52) **U.S. Cl.**
USPC ..... **606/80**

(58) **Field of Classification Search**
USPC ..... 606/79–85, 86 R; 623/17.11–17.16; 408/204–206
See application file for complete search history.

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(74) *Attorney, Agent, or Firm* — McGlew and Tuttle, P.C.

(57) **ABSTRACT**

A cutter for spine surgery is provided, especially for use in the area of the delicate cervical spine. The cutter includes a cylindrical cutter shank with cutter teeth formed at the distal end thereof. The cutter teeth at the distal end of the cutter shank are formed by grooves in the wall of the cutter shank. The grooves become deeper and expand from the outer radius of the cutter shank towards the distal end such that teeth narrowing towards the distal end with increasing height are formed between them. This guarantees especially gentle cutting in the area of the cervical spine, without surrounding delicate tissue being additionally jeopardized.

**13 Claims, 2 Drawing Sheets**

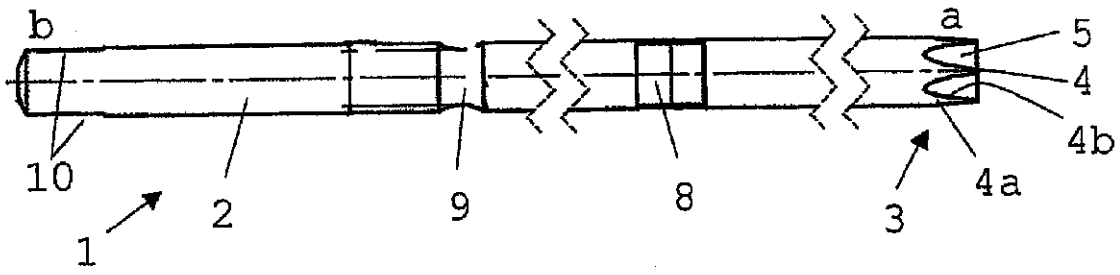


**Fig. 1**

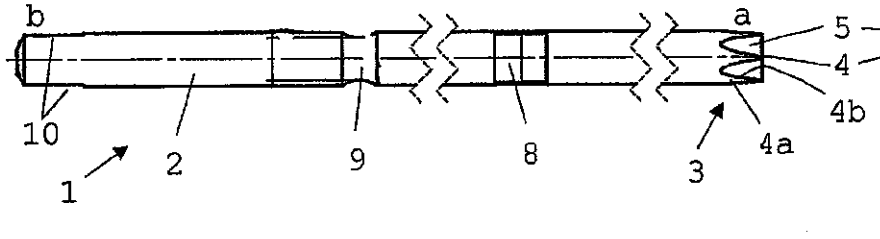



**Fig. 1a**

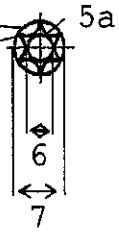



**Fig. 2**

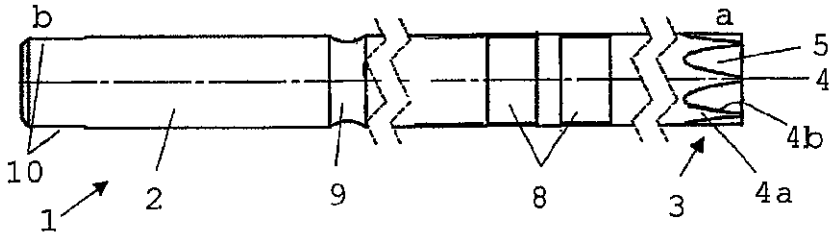



**Fig. 2a**

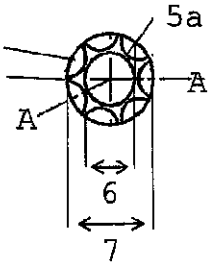



**Fig. 3**

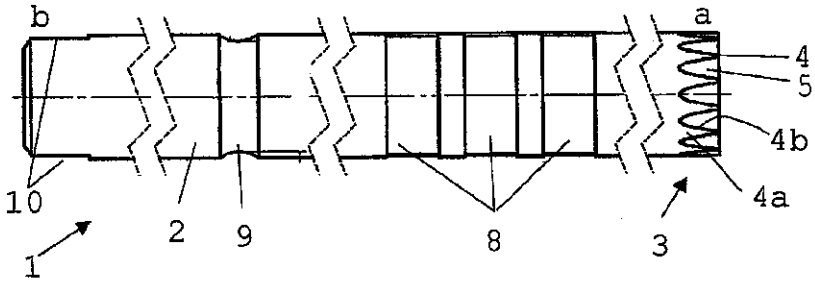



**Fig. 3a**

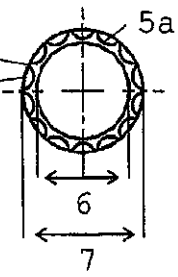



**Fig. 4**
**A - A**

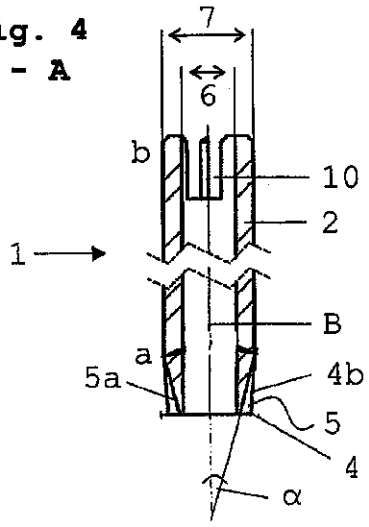


**Fig. 5**

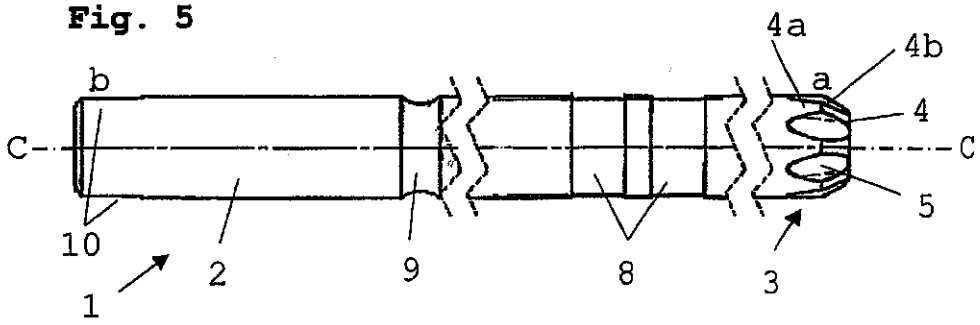
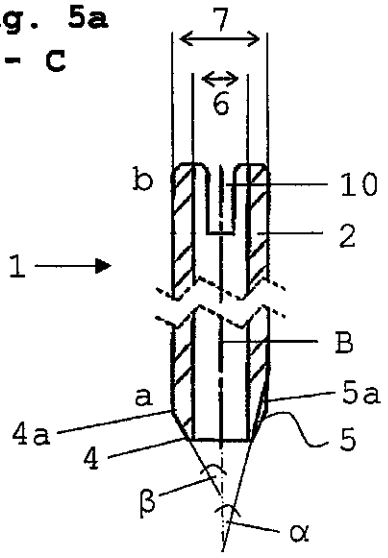



**Fig. 5a**
**C - C**



# SPINE CUTTER

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority under 35 U.S.C. §119 of German Patent Application DE 20 2009 006 792.0 filed May 12, 2009, the entire contents of which are incorporated herein by reference.

## FIELD OF THE INVENTION

The present invention pertains to a cutter for spine surgery, especially for use in the area of the cervical spine, with a cylindrical cutter shank and cutter teeth formed at the distal end thereof, as well as with a cutter set comprising the aforementioned cutters.

## BACKGROUND OF THE INVENTION

A cutter of this type is known from DE 20 2005 016 763 U1 and describes a facet joint cutter, which is used to cut out vertebral components in the area of the spine. This cutter has a cylindrical shank and sawtooth-like teeth formed at its front-side, distal end. The teeth point forward from the distal end, and said teeth are slightly expanded outwardly. The teeth are directed parallel to the axis, and grooves, which likewise extend parallel to the axis and extend radially from the internal diameter of the cutter wall up to the external diameter, are located between them.

It was found that the bone material cannot be cut out sufficiently gently, especially from the delicate cervical vertebrae, with the prior-art cutters.

## SUMMARY OF THE INVENTION

The basic object of the present invention is therefore to create improved cutters for endoscopic spine surgery while avoiding the aforementioned drawbacks.

This object is accomplished with a cutter of the type mentioned in the introduction by the teeth of the cutter at the distal end of the cutter shank being formed by grooves in the wall of the cutter shank, which deepen and expand from the outer radius of the cutter shank towards the distal end such that teeth narrowing towards the distal end with increasing height are formed between them.

Due to the teeth modified compared to the state of the art, which are formed in a star-shaped pattern on the distal front side of the cutter shank such that the front side of the teeth point from the inner wall side of the shank radially outwardly, and especially with a flat front-side closure, wherein the cutting edges are formed at the edge of the front side, more gentle cutting is achieved along with uniform precision and cutting action. The base of the grooves between the teeth, the groove base, is closed; consequently, no slots extending completely radially through the shank wall are formed between the teeth. The tooth flanks extending in the wall of the cylindrical shank are directed outwardly in a star-shaped pattern on the front side. Great sharpness of the teeth of the individual cutters is nevertheless guaranteed.

The teeth are separated by grooves, the grooves cut expand parabolically in the axial direction towards a distal end facing the vertebra to be cut and the teeth have a transition edge corresponding to the shape of the groove between the groove and the tooth wall. The groove bases have an angle of at least 13° to 15° in relation to a longitudinal axis of the cutter. Furthermore, the present invention makes provisions for the



teeth defined by tooth walls becoming pointed parallel to the axis and/or for the edges of the tooth walls becoming pointed towards the distal end parallel to the axis, and provisions may also be made for the tooth walls becoming pointed towards the distal end beginning from half of their groove length. Outer edges of the tooth walls are extremely preferably located on an external diameter of the cutter shank, and the cutting edges may also be formed on the front side. This makes possible an especially gentle cutting without surrounding delicate tissue being jeopardized. Such a cutter can be used as a cervical spine cutter especially for the cervical spine. Preferred variants of such a cutter make provisions for outer edges of the teeth to be located on an external diameter of the cutter shank and/or for edges of the tooth walls to become pointed towards the distal end parallel to the axis.

In another preferred embodiment the teeth have bent outer tooth walls, and the tooth walls extend parallel to the axis over up to half the length of the grooves and at an angle of at least 30° in relation to the longitudinal axis of the cutter towards the distal end. Provisions may be made here for the teeth having sharp cutting edges at the obliquely extending transition edges. Thus, sharp cutting edges of the teeth are formed in all embodiments of the cutter at the front-side end or in the obliquely extending area only.

In a preferred embodiment, the shank has at least one or more colored ceramic rings towards a proximal end for better distinction of cutters of different sizes, the heat-resistant ceramic rings being more durable and resistant than colored rings made of plastic.

An annular recess, with which the cutter can be clamped in a corresponding handling or rotating device, is formed on the shank of the cutter according to the present invention, and at least two rectangular slots are formed at a proximal end in another embodiment, and a torque can be transmitted to the cutter due to positive-locking connection with the handling or rotating device.

The cutter preferably has 4 to 8 teeth at an internal diameter of less than 2 mm of its wall, 5 to 10 teeth at an internal diameter of 2 mm to 2.5 mm, 10 to 16 teeth at an internal diameter of 3 mm to 4 mm and 12 to 24 teeth at an internal diameter greater than 5 mm.

A set of cutters, comprising at least three cutters, is preferably provided, wherein a first cutter has an external diameter that corresponds, possibly taking tolerances into account, at most to an internal diameter of a next larger cutter. The external and internal diameters of the cutters are thus very preferably coordinated such that the cutters can be pushed one into the other. At least one cutter of a set of cutters has an external diameter greater than 5 mm.

Other advantages and features appear from the claims and from the following description, in which an exemplary embodiment of the present invention is specifically explained with reference to the drawings. The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses, reference is made to the accompanying drawings and descriptive matter in which preferred embodiments of the invention are illustrated.

## BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a schematic enlarged view of a first cutter, according to the present invention, with an external diameter of 2 mm;

FIG. **1***a* is a schematic view of the front side of the cutter according to the present invention from FIG. **1**;

FIG. **2** is a schematic enlarged view of another cutter according to the present invention with an external diameter of 3.6 mm;

FIG. **2***a* is a schematic view of the front side of the cutter according to the present invention from FIG. **2**;

FIG. **3** is a schematic enlarged view of another cutter according to the present invention with an external diameter of 4.7 mm;

FIG. **3***a* is a schematic view of the front side of the cutter according to the present invention from FIG. **3**;

FIG. **4** is a schematic sectional view of a cutter according to the present invention in section A-A from FIG. **2***a*;

FIG. **5** is a schematic enlarged view of another cutter according to the present invention with another embodiment of the teeth; and

FIG. **5***a* is a schematic sectional view of a cutter according to the present invention in sectional view C-C from FIG. **5**.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings in particular, FIGS. **1**, **2** and **3** show a schematic view each of cutters **1** according to the present invention and the cutters **1** together form a set of cutters **1** of different sizes. Serrated lines in the figures indicate a shortening of the length in the drawing for the sake of greater clarity.

A cutter **1**, as it is shown in the exemplary embodiment according to FIG. **1** or FIG. **1***a*, has a cylindrical shank **2**, which is formed from a long steel tube. A front-side, distal end a of cutter **1** is formed as a set of cutter teeth **3**, which comprise teeth **4** and grooves **5** located between them. Grooves **5** are cut in the axial direction parabolically into the wall of shank **2**, and the grooves **5** expand radially as well as axially towards the distal end a. Thus, they show a partly conical incision in the wall of shank **2**. The teeth **4** are formed from the tooth walls **4***a* left behind after the grooves **5** have been cut out, the tooth walls **4***a* becoming pointed parallel to the axis towards the distal end a. A transition edge **4***b* corresponding to the parabolic shape of groove **5** is formed between the tooth wall **4***a* and the groove **5**. Transition edge **4***b* may have a sharpened edge. Grooves **5** and the adjoining tooth walls **4***a* thus show an axial direction of the main course parallel to the axis, so that the teeth **4** formed are located on the external diameter of shank **2**. Cutter **1** has a flat closure on the front side. This flat closure brings about the formation of a sharp cutting edge of the teeth **4** at the front-side, distal end a. As an alternative, a bent closure may also be provided, which will be explained in more detail below in FIGS. **5** and **5***a*.

Furthermore, shank **2** of cutter **1** has a recessed colored ceramic ring **8** with a width of about 2 mm. The cutters **1** in FIGS. **2** and **3** have not only a colored ceramic ring **8**, but correspondingly two or three colored ceramic rings **8**. It is thus possible to distinguish the different cutters by means of the number and color of the ceramic rings **8**. Furthermore, shank **2** has an annular recess **9**, whose center is located at a distance of 13 mm from a proximal end b located opposite the distal end a in the exemplary embodiment according to FIGS. **1-3** and which is used to axially fasten the cutter **1** in a corresponding handling or rotating device.

The set of cutter teeth **3** are shown, furthermore, in a schematic front view in FIGS. **1***a*, **2***a* and **3***a* for the respective sizes of the cutters **1**, showing that the teeth **4** are shaped radially outwardly, i.e., in a star-shaped pattern, in one plane



on the cutter head due to the correspondingly cut grooves **5** and the flat closure at the distal end a. In the front-side view, the grooves **5** cut point-symmetrical as circle segments towards the center of the front-side radial plane have a certain depth **5**, which is defined by a thin wall to an internal diameter **6**. The teeth **4** are arranged each at right angles to the circumference of the cutter head, and their outer edges are located on an external diameter **7** of shank **2**. The outer edges are defined by the pointed transition edge **4***b*, as a result of which a sharp outer cutting edge of teeth **4** is obtained at the front-side distal end a.

FIG. **4** shows a longitudinal section through cutter **1** through the connection A-A in FIG. **2***a*. Furthermore, the distal end a with the set of teeth **3** with teeth **4** and grooves **5** is again shown in FIG. **4** in a longitudinal section by a shortening of the drawing, the grooves **5** having a groove base **5***a*. Groove base **5***a* changes here over the length of the grooves **5** radially with the axial height at a certain angle $\alpha$ towards a longitudinal axis B and ends on the front side at the distal end a. This angle $\alpha$ equals approx. 15° for the cutters **1** from FIGS. **1** and **2** and the angle $\alpha$ equals approx. 13° for cutter **1** from FIG. **3**. It can be clearly recognized here that the teeth **4** are located on the external diameter **7** of shank **2**.

Furthermore, at least two opposite rectangular slots **10**, by means of which a torque can be transmitted to the cutter **1** by positive-locking connection with a corresponding handling or rotating device, are formed at the proximal end b of shank **2**.

FIGS. **5** and **5***a* show an alternative embodiment of the teeth of cutter **1** according to the present invention with a bent closure at the distal end a. The teeth are again formed by grooves **5** cut parabolically in the wall of cutter **1** in the axial direction, wherein the tooth walls **4***a* formed hereby are at first parallel to the axis towards the distal end a. Beginning from half the length of the grooves **5**, the tooth walls **4***a* are bent radially inwardly. The groove bases **5***a* are made pointed towards the distal end a, and the tooth walls **4***a* have a nearly constant width. Due to the flat front-side closure, a sharp cutting edge is obtained directly on the front side. An additional cutting edge may be formed in the obliquely extending area of the tooth walls **4***a*.

FIG. **5***a* shows for this a longitudinal section according to section C-C, with shortening of the drawing for the sake of greater clarity, through the cutter **1** in FIG. **5**. For the variant of the teeth **3** being shown here, the groove base **5***a* of the grooves **5** likewise varies radially with the axial height with the angle $\alpha$ towards the longitudinal axis B and ends on the front side at the distal end a. As was already described in FIG. **5**, the tooth walls **4***a* do not extend parallel to the axis over their entire length, but are bent beginning from half of the length of groove **5** at an angle $\beta$ towards the longitudinal axis B of cutter **1** and likewise end at the distal end a on the front side. This variant of the teeth **3** has values of $\alpha$=13°-15° and $\beta$=30°.

In this exemplary embodiment the cutters **1** according to FIGS. **1-3** cover, furthermore, as a set of cutters the following dimensions of the internal diameter **6**, external diameter **7**, number of teeth **4** and overall length of the cutter **1**:

| Internal diameter 6 [mm] | External diameter 7 [mm] | Number of teeth 4 | Overall length of cutter 1 [mm] |
|---|---|---|---|
| 1 | 2 | 6 | 250 |
| 2.1 | 3.6 | 7 | 230 |
| 3.7 | 4.7 | 14 | 210 |

The cutters **1** from FIGS. **1** and **3** have a wall with a thickness of about 0.5 mm. The cutter in FIG. **2** has for this a wall thickness of about 0.75 mm. Besides the dimensions listed here, cutters **1** with an external diameter **7** greater than 5 mm with up to 24 teeth are also provided with the corresponding other dimensions adapted hereto.

Due to the diameters coordinated with one another, in which the external diameter **7** of a thin cutter **1** fits the internal diameter **6** of the next thicker cutter **1** with a tolerance of 0.1 mm, the cutters **1** as a set of cutters can be optimally pushed one into the other, so that they can be placed for this one over another and/or split up for hollowing out in a vertebra. They can be distinguished in their different sizes not only by the different external diameters **7**, but also by the different number of colored ceramic rings **8** consisting of heat-resistant ceramic. Common to all is the annular recess **9** and the rectangular slot **10** at the proximal end b of shank **2**, which make it possible to firmly clamp the cutters **1** in a corresponding handling or rotating device and to transmit a torque due to positive-locking connection with the handling or rotating device, as a result of which precise operation is made possible in endoscopic spine surgery.

While specific embodiments of the invention have been described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.

What is claimed is:

**1**. A set of at least three cutters, each of the at least three cutters comprising:

a cylindrical cutter shank with a cylindrical wall and an inner circumferential inner surface, said cylindrical wall having a continuous outer cylindrical wall surface and a longitudinal axis, said outer cylindrical wall surface defining a plurality of outer radial extents and a plurality of inner radial extents at a distal end of said shank, said outer radial extents defining a plurality of teeth of said cylindrical wall, said outer radial extents and said inner radial extents defining a plurality of grooves in said cylindrical wall, each of said grooves being located between one of said outer radial extents and another one of said outer radial extents, each of said outer radial extents being located at a position that is radially outward of one or more of said inner radial extents, each of said outer radial extents extending from an outer radial extent position to said distal end, said outer radial extent position being located at a spaced location from said distal end, each of said inner radial extents extending from an inner radial extent position to said distal end, said inner radial position being located at a spaced location from said distal end, wherein a thickness of each of said inner radial extents decreases from said inner radial extent position to said distal end with respect to the longitudinal axis and a width of each of said outer radial extents decreases from said outer radial extent position to said distal end with respect to the longitudinal axis, whereby a depth of said grooves increases towards the distal end with respect to the longitudinal axis and a distance between each of said outer radial extents and another one of said outer radial extents increases from said outer radial extent position to said distal end,



wherein a first cutter has an external diameter that corresponds at most to an internal diameter of a next larger second cutter and the second cutter has an external diameter that corresponds at most to an internal diameter of a further larger third cutter whereby the cutters can be pushed one into the other.

**2**. A spine cutter in accordance with claim **1**, wherein each of said teeth extends parallel to said longitudinal axis.

**3**. A spine cutter in accordance with claim **1**, wherein outer tooth walls extend parallel in relation to said longitudinal axis up to half a length of the grooves and a cutting edge of the teeth extends at an angle of at least 30° in relation to said longitudinal axis towards the distal end.

**4**. A spine cutter in accordance with claim **3**, wherein tooth flanks become pointed beginning from half the length of the grooves towards the distal end.

**5**. A spine cutter in accordance with claim **1**, wherein the teeth have sharp cutting edges at obliquely extending transition edges.

**6**. A spine cutter in accordance with claim **1**, wherein the cylindrical cutter shank has at least one or more colored ceramic rings towards a proximal end for marking the cylindrical cutter shank for distinction of cutters of different sizes.

**7**. A spine cutter in accordance with claim **1**, wherein an annular recess is formed on the cylindrical cutter shank for fastening the cylindrical cutter shank in a handling or rotating device and at least two opposite rectangular slots are formed at a proximal end of the cylindrical cutter shank, wherein a torque can be transmitted to the cylindrical cutter shank by positive-locking connection of the cylindrical cutter shank with the handling or rotating device, said inner circumferential inner surface defining a hollow space at said distal end.

**8**. A spine cutter in accordance with claim **1**, wherein the teeth extend parallel in relation to said longitudinal axis.

**9**. A set of cutters in accordance with claim **1**, wherein

the first cutter has an internal diameter of 1 mm and an external diameter of 2 mm;

the second cutter has an internal diameter of 2.1 mm and an external diameter of 3.6 mm; and

the third cutter has an internal diameter of 3.7 mm and an external diameter of 4.7 mm.

**10**. A set of cutters in accordance with claim **1**, wherein each of the grooves expand, in an axial direction with respect to said longitudinal axis, parabolically towards the distal end, each of said outer radial extents being located at a distance from said longitudinal axis that is greater than a distance between each of said inner radial extents and said longitudinal axis, each of said outer radial extents extending parallel to said longitudinal axis.

**11**. A set of cutters in accordance with claim **1**, wherein said cutter teeth have a transition edge corresponding to a groove shape between at least one of the grooves and a tooth wall.

**12**. A set of cutters in accordance with claim **1**, wherein groove bases of said grooves have an angle of at least 13°-15° in relation to said longitudinal axis of each cutter.

**13**. A spine cutter in accordance with claim **1**, wherein front-side distal cutting edges of said outer radial extents are located in a radial plane.

* * * * *

# EXHIBIT "E"

US008623021B2

(12) **United States Patent**
**Ries et al.**

(10) **Patent No.: US 8,623,021 B2**
(45) **Date of Patent: Jan. 7, 2014**

(54) **FACET JOINT REAMER**

(75) Inventors: **Wolfgang Ries**, Linkenheim (DE); **Mathias Notheis**, Forst (DE)

(73) Assignee: **Joimax GmbH**, Karlsruhe (DE)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1121 days.

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(52) **U.S. Cl.**
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(58) **Field of Classification Search**
USPC ..... 606/79–86 R, 167, 178, 184, 185; 407/29.1, 29.13, 29.15; 408/204, 206
See application file for complete search history.

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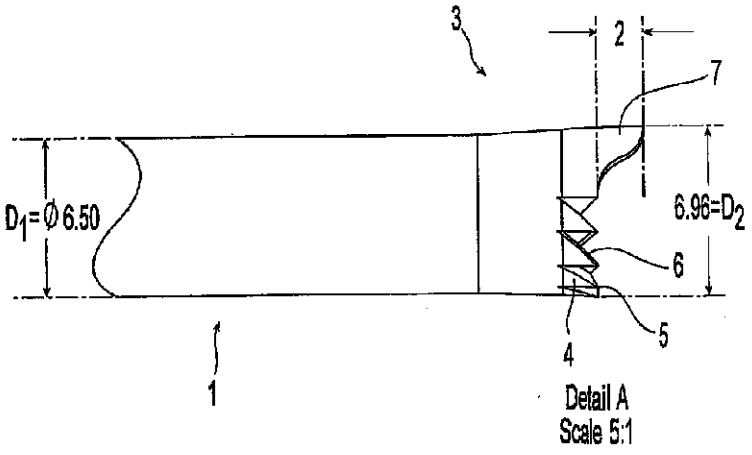
*Primary Examiner* — Kevin Truong
*Assistant Examiner* — Matthew Lawson
(74) *Attorney, Agent, or Firm* — McGlew and Tuttle, P.C.

(57) **ABSTRACT**

In a facet joint reamer with a shank and teeth at the distal end, the distal end is widened compared with the remainder of the shank.

**18 Claims, 5 Drawing Sheets**



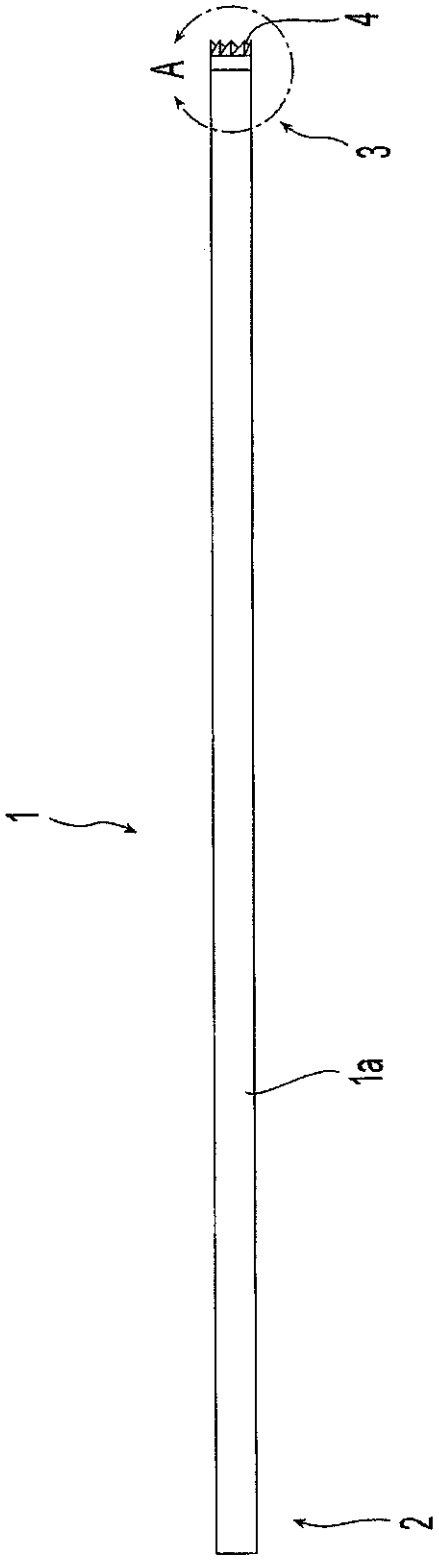



Fig. 1

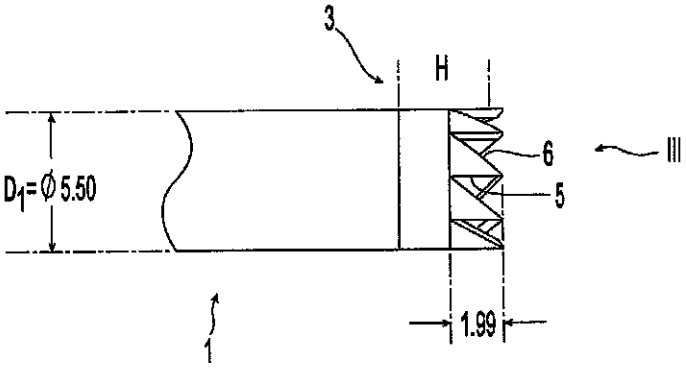



*Fig. 2*

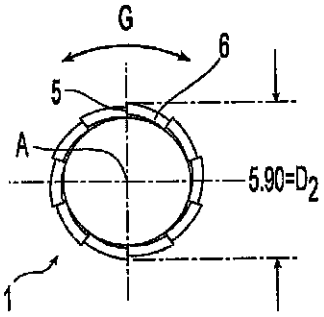



*Fig. 3*

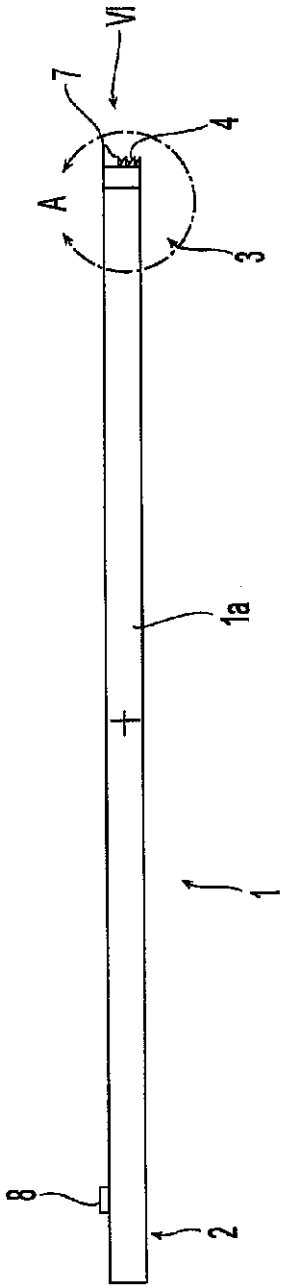



Fig. 4

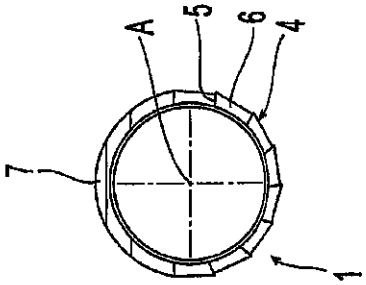



Fig. 6

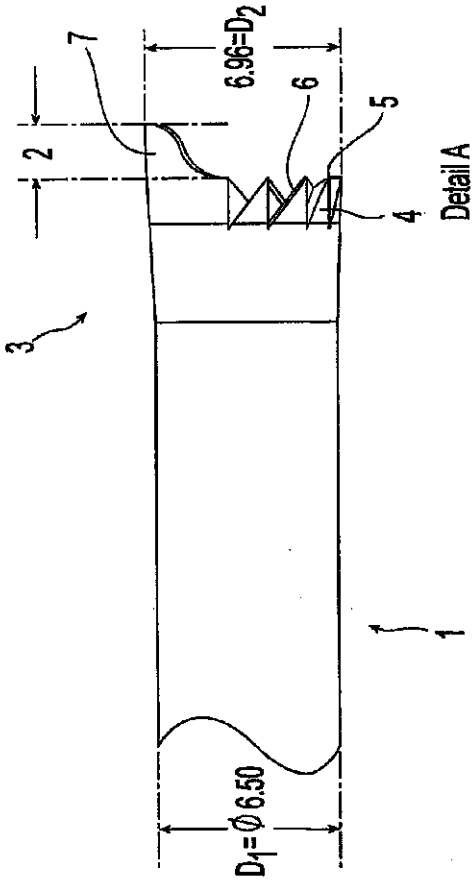



Fig. 5

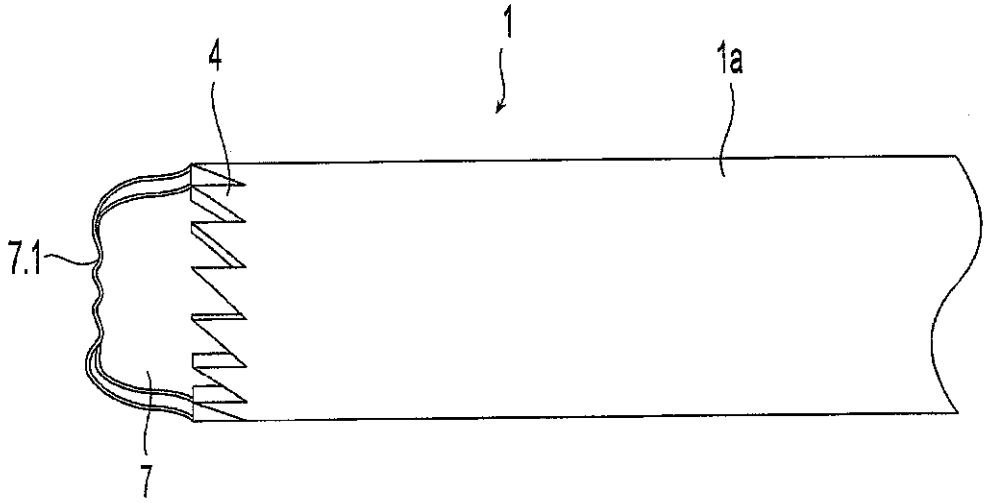
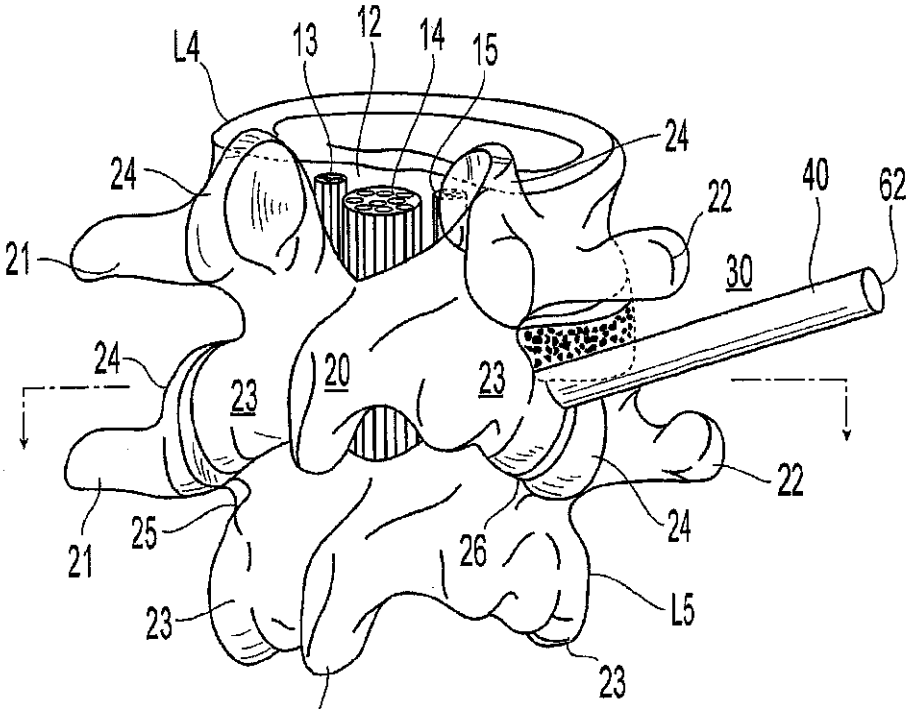



*Fig. 7*


L4
13
12
14
15
24
24
22
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62
21
30
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23
23
22
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L5
23
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Fig. 8

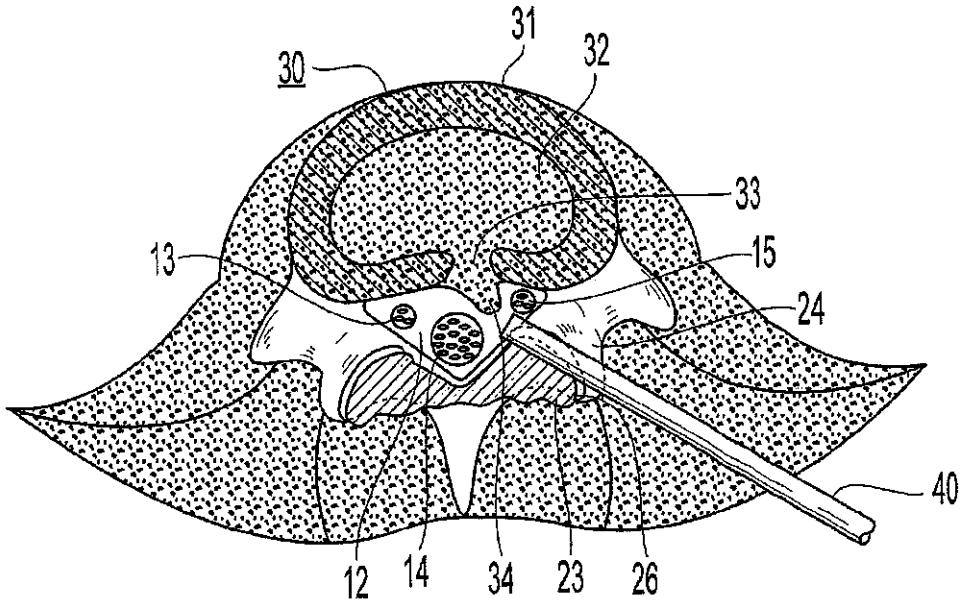
31
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Fig. 9

# FACET JOINT REAMER

## FIELD OF THE INVENTION

The invention relates to a facet joint reamer having a shank and teeth at the distal end.

## BACKGROUND OF THE INVENTION

Such a facet joint reamer, also commonly known as a facet joint milling cutter, is known from DE 699 17 683 T2. The known reamer has a hollow cylindrical shank, a handle at its rear, proximal end and teeth at its front end.

Such a reamer is used for cutting out vertebral components in the vicinity of a lateral process of a vertebral column vertebra in order to create postero-lateral access to strangulated nerve roots of the central nervous system. Through said access it is then possible to remove intervertebral disk pulp tissue and other tissue types (capsular, cicatricial and ring tissue), because they press on the nerve roots. Said process of a vertebra forms the facet joint with an adjacent process of an adjacent vertebra.

The microinvasive surgery method for the decompression of strangulated nerve roots using such a facet joint reamer is highly successful. However, it has been found that the bone material cut out by the reamer is not adequately removed from the cutting out area.

An object of the invention is therefore to so further develop such a facet joint reamer that it is possible to reliably remove cut out bone material.

## SUMMARY OF THE INVENTION

According to the invention this object is solved in the case of a facet joint reamer of the aforementioned type in that the distal end of the reamer is widened compared with the shank diameter.

As a result of the widening of the distal end of the facet joint reamer, particularly over the height of the reamer teeth, but preferably up to roughly twice the height of the reamer teeth, the entry of cut out bone material into the reamer interior is improved and can, if necessary, be sucked off. The widening extends constantly and continuously from the reamer shank cross-section to the maximum widening at the front end of the teeth and is between 0.2 and 0.6 mm, preferably 0.4 mm, so that the reamer diameter at the front end of the teeth is between 0.2 and 0.6 mm, preferably 0.4 mm more than the cylindrical shank diameter.

An extremely preferred facet joint reamer is characterized by a lip axially projecting over the teeth and extending over a partial circumference, the extension arc or angle being between 140 and 160°, preferably 150°. The axial height of the lip is preferably in a range 1 to 3 mm.

The lip is deburred and its edges rounded. It is used for protecting the nerve when the reamer is used close to the latter, so that said nerve is not injured by the cutting process. For orientation purposes the proximal, i.e. the teeth-remote end of the reamer is provided with a marking, e.g. an elevated rib corresponding to the lip position.

Particularly in the case of a reamer constructed with such a lip said reamer is not completely rotated and is instead rotated backwards and forwards in oscillating manner, so that the teeth are always in engagement with the bone material.

## BRIEF DESCRIPTION OF THE DRAWINGS

Further advantages and features of the invention can be gathered from the claims and subsequent description of an embodiment of the invention with reference to the attached drawings, wherein show:



FIG. **1** An inventive reamer in side view.

FIG. **2** A larger scale representation of the distal or head end of the reamer of FIG. **1**.

FIG. **3** A view of the distal end of the reamer of FIG. **2** along arrow III thereof.

FIG. **4** A side view of a particularly preferred development of an inventive reamer.

FIG. **5** The distal end of the reamer of FIG. **4** on a larger scale.

FIG. **6** A front view corresponding to VI in FIG. **4** of said reamer.

FIG. **7** A front end of an inventive reamer with a rasp-formed lip.

FIG. **8** A rear view of two adjacent lumbar vertebrae of the human vertebral column.

FIG. **9** A part sectional view of the spinal intervertebral disks between the two vertebrae in FIG. **7**.

## DETAILED DESCRIPTION OF THE DRAWINGS

The facet joint reamer according to the invention has a shank **1***a*, preferably with a length between 18 and 25 cm and in the embodiment shown roughly 21 cm. At its rear or surgeon-pointing, proximal end **2** the reamer **1** is either provided with a handle or with a fastening device for the releasable fastening to a handle, the latter preferably being made from plastic. Neither the fastening device nor the handle are shown in detail.

Teeth **4** are located at its front or distal end **3**. In the embodiment shown the teeth **4** have an asymmetrical construction. On viewing the front end according to FIG. **3**, the front flank **5**, parallel to axis A, is directed counterclock-wise G, whereas the rear flank **6** is chamfered and has an inclination angle of 35 to 45°, preferably approximately 40° to axis A. In the rotation direction when working the front flank **5** is the active, cutting flank.

As can in particular be gathered from FIGS. **2** and **3**, the front end of reamer **1** is widened compared with the diameter of shank **1***a*. Whereas in the embodiment shown the shank has a diameter of 5.5 mm, the distal end of the reamer has a diameter of 5.9 mm in the vicinity of teeth **4**. Thus, there is a 0.4 mm widening. Preferably the widening is in the range approximately 0.8 mm or 2% of the diameter up to 0.6 mm with a tolerance of 0.01 mm. Diameter $D_1$ of shank **1***a* up to diameter $D_2$ of the front end of teeth **4** extends over a height H, i.e. 2 mm, so that the height H of the widening area is approximately 4 mm and can preferably be up to 6 mm.

As a result of the widening the cut out bone material enters the reamer interior and therefore out of the working area and can consequently be removed from the patient's body, e.g. by sucking through the reamer interior.

FIGS. **4** to **6** show a further extremely preferred development of the inventive reamer. To the extent that identical parts are present, the same reference numerals are used. In connection with said common parts reference is made to the explanations concerning FIGS. **1** to **3**.

Unlike in the reamer of FIGS. **1** to **3**, reamer **1** of FIGS. **4** to **6** has a lip **7** projecting axially over a partial circumference or arc of the shank jacket. The arcuate extension runs over an angle of 150° in the embodiment shown and the height of lip **7** over and beyond the crests of the teeth and independently of the reamer diameter is approximately 2 mm. The lip is deburred and the edges rounded. Thus, an adjacent nerve is protected when working in the vicinity of a nerve by lip **7**, so that the cutting operation does not injure the nerve.

In the development of FIG. **7** the front end of the lip **4** is in the form of a rasp **7.1** with wavy teeth. Thus, in the case of

swivelling movements under pressure soft tissue parts, such as periosteum can be removed, whereas harder nerve skin is not damaged by such a rasp **7.1**.

For orientation purposes the proximal end **2** of reamer **1** is provided with a marking **8** corresponding to the position of lip **7**, i.e. is axially aligned therewith.

The reamer according to the invention is used in the manner described hereinafter relative to FIGS. **8** and **9**.

FIG. **8** shows in exemplified manner the fourth and fifth lumbar vertebrae L4, L5 and between the same an intervertebral disk **30** with a strangulation **33** at the fibrous ring **31** immediately to the right of the central axis of the vertebral column with an extrusion **34** of intervertebral disk pulp tissue into the vertebral canal FIG. **9**.

Nerve structures **13**, **14**, **15** are diagrammatically illustrated in the interior of the vertebral canal **12**. Each vertebra L4, L5 has a spinous process **20** and a left and right-hand transverse process **22**, left and right-hand, lower, joint-forming processes **23** and left and right-hand, upper, joint-forming processes **24**, the left and right-hand joint between the upper and lower lumbar vertebra L4, L5, referred to as the facet joint **26** being formed by in each case the lower processes **23** of the upper vertebra L4 and the upper processes **24** of the lower vertebra L5.

The reamer according to the invention is used in the following way:

Firstly a hollow needle or probe with an external diameter of approximately 1.25 mm is advanced into a position adjacent to the strangulation. A guide wire is then passed through the lumen until its distal end projects somewhat over the end of the hollow probe. The hollow probe is then removed, whereas the guide wire remains in place. A guide rod with an external diameter of 2.5 mm (also constructed as a dilator) is advanced over the guide wire until the conical end of the guide rod (external diameter 2.5 mm) is at the facet joint **26**. A guide sleeve (external diameter 3.8 mm), which is conical at the distal end, is then engaged over the guide rod for further tissue dilation and reamer guidance. Whilst holding the guide rod with guide sleeve in this position an inventive reamer with a small diameter approximately the same as the internal diameter 4.2 mm, external diameter 5.0 mm is advanced over the guide rod and guide sleeve **52** until the distal reamer end engages on the surface of the facet joint **26**.

The surgeon then rotates, e.g. manually and preferably in oscillating manner the handle located at the reamer end close to him, so that in the protuberance **23** of vertebra L4 a channel is produced. This step is repeated with guide rods, guide sleeves and reamers with a larger diameter until an adequate channel diameter is obtained in order to receive a working cannula with a lumen which is sufficiently large to be able to guide through not only forceps, but also an endoscope. The strangulation **33** is then removed with the forceps, optionally under endoscopic observation.

Reference Numerals List

**1** Reamer
**1***a* Shank
**2** Proximal end
**3** Distal end
**4** Teeth
**5** Front flank
**6** Rear flank
**7** Lip
**7.1** Rasp
**12** Vertebral canal
**13**, **14**, **15** Nerve structures
**20** Spinous process
**22** Transverse process
**23**, **24** Processes
**26** Facet joint
**30** intervertebral disk
**31** Fibrous ring
**33** Strangulation
**34** Extrusion
A Axis
$D_1$, $D_2$ Diameter
G Counterclockwise (=rotation direction)
H Height
L4, L5 Lumbar vertebrae



The invention claimed is:

**1**. A facet joint reamer for creating a postero-lateral access through a vertebral column, the facet joint reamer comprising:

a shank extending along a rotary axis and having a distal end portion extending from a main shank portion, said shank being rotatable about said rotary axis;

a plurality of teeth, each tooth of said plurality of teeth being adjacent to another tooth of said plurality of teeth, at least a portion of said distal end portion forming said plurality of teeth at said distal end portion of said shank, said plurality of teeth extending around at least a teeth section of a circular circumference of said shank centered on the rotary axis, each of the teeth having a front flank extending parallel to the rotary axis, wherein the distal end portion is wider in diameter than the main shank portion; and

a lip, at least another portion of said distal end portion forming said lip at a distal end of said shank, said lip extending over a part of the circumference and said lip projecting along said rotary axis distally over the teeth, said lip being integrally connected to said distal end of said shank, said lip encompassing between 140 and 160 degrees of said circular circumference of said shank, said teeth section comprising a remainder of said circular circumference of said shank.

**2**. The reamer according to claim **1**, wherein the wider-diameter distal end portion defines a circumferential widening that extends at least over a height of the teeth.

**3**. The reamer according to claim **2**, wherein the widening extends over double the height of the teeth.

**4**. The reamer according to claim **2**, wherein the widening is continuous and constant from the diameter of the main shank portion to a maximum diameter of the widening at crests of the teeth.

**5**. The reamer according to claim **4**, wherein the widening extends over a length between 4 and 6 mm to the crests of the teeth.

**6**. The reamer according to claim **5**, wherein the widening at the crests is 0.4 mm.

**7**. The reamer according to claim **1**, wherein the lip projects over the teeth by 1 to 3 mm.

**8**. The reamer according to claim **1**, wherein at least a front end of the lip comprises a rasp.

**9**. The reamer according to claim **1**, wherein the lip extends 150 degrees.

**10**. The reamer according to claim **1**, wherein said shank is integrally connected with said distal end to form a one-piece shank structure.

**11**. A facet joint reamer for creating a postero-lateral access through a vertebral column, the facet joint reamer comprising:

a shank extending along a rotary axis, said shank being rotatable about said rotary axis, said shank having a distal end portion and a main shank portion, said distal end portion extending from said main shank portion,

said distal end portion having a distal end surface, said distal end surface defining a lip and defining a plurality of teeth, wherein said lip is integrally connected to said distal end portion of said shank, each of said plurality of teeth being adjacent to another one of said plurality of teeth, said plurality of teeth defining a first circumferential end portion of said shank, said lip defining a second circumferential end portion of said shank, said first circumferential portion being centered with respect to the rotary axis, said second circumferential end portion extending over an arc of 140 to 160 degrees of a circumference of said distal end surface, said first circumferential end portion extending over a remainder of said circumference of said distal end surface, each of said teeth having a front flank extending parallel to the rotary axis, wherein the distal end portion has a distal end portion diameter, said main shank portion having a main shank portion diameter, said distal end portion diameter being greater than said main shank portion diameter, each of said teeth having a tooth end, said lip having a lip end, said lip end projecting distally beyond said tooth end of each of said teeth along the rotary axis, at least a portion of said lip extending between one of said plurality of teeth and another one of said plurality of teeth, said lip defining a means for engaging a nerve structure such that said lip maintains the nerve structure at a spaced location from said plurality of teeth.

**12**. The reamer according to claim **11**, wherein the wider-diameter distal end portion defines a circumferential widening that extends at least over a height of the teeth.

**13**. The reamer according to claim **12**, wherein the widening extends over double the height of the teeth.

**14**. The reamer according to claim **12**, wherein the widening is continuous and constant from the diameter of the main shank portion to a maximum diameter of the widening at crests of the teeth.

**15**. The reamer according to claim **14**, wherein the widening extends over a length between 4 and 6 mm wider to the crests of the teeth.

**16**. The reamer according to claim **15**, wherein the widening at the crests is 0.4 mm.

**17**. The reamer according to claim **11**, wherein the lip projects over the teeth by 1 to 3 mm.

**18**. The reamer according to claim **11**, wherein at least a front end of the lip is configured as a rasp, wherein the lip extends over an arc of 150 degrees.

* * * * *

# EXHIBIT "F"

US008821378B2

(12) **United States Patent**
**Morgenstern Lopez et al.**

(10) **Patent No.: US 8,821,378 B2**
(45) **Date of Patent: Sep. 2, 2014**

(54) **DEVICE AND METHOD FOR MINIMALLY INVASIVE SPINAL INTERVENTION**

(75) Inventors: **Rudolf Morgenstern Lopez**, Esplugues de Llobregat (ES); **Wolfgang Ries**, Linkenheim (DE)

(73) Assignee: **Joimax GmbH**, Karlsruhe (DE)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 893 days.

(21) Appl. No.: **12/516,316**

(22) PCT Filed: **Nov. 24, 2007**

(86) PCT No.: **PCT/EP2007/010238**

§ 371 (c)(1),
(2), (4) Date: **May 26, 2009**

(87) PCT Pub. No.: **WO2008/064842**

PCT Pub. Date: **Jun. 5, 2008**

(65) **Prior Publication Data**

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(30) **Foreign Application Priority Data**

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(51) **Int. Cl.**
***A61B 17/16*** (2006.01)

(52) **U.S. Cl.**
USPC ..... **600/107**; 606/79

(58) **Field of Classification Search**
CPC ..... A61B 1/00; A61B 17/16; A61B 17/1671
USPC ..... 606/79–85, 86 R, 181–185, 190; 623/17.11–17.16; 600/114
See application file for complete search history.

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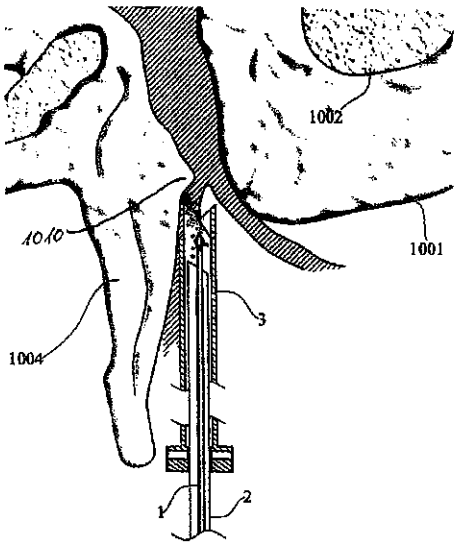
*Primary Examiner* — Christopher Beccia
(74) *Attorney, Agent, or Firm* — McGlew and Tuttle, P.C.

(57) **ABSTRACT**

The invention proposes a device for minimally invasive intervention in the skeletal region, in particular on the spinal column, having at least a cannula with a distal end generally bevelled in shape relative to a symmetrical axis of the cutting tool and an optical probe (endoscope) for insertion through the cavity of the cannula. The device is further characterized in that the cannula takes the form of a hollow cutting tool, in which the most distal region of the distal end comprises a cutting edge, which is incorporated into the edge of the wall of the cutting tool.

**78 Claims, 21 Drawing Sheets**



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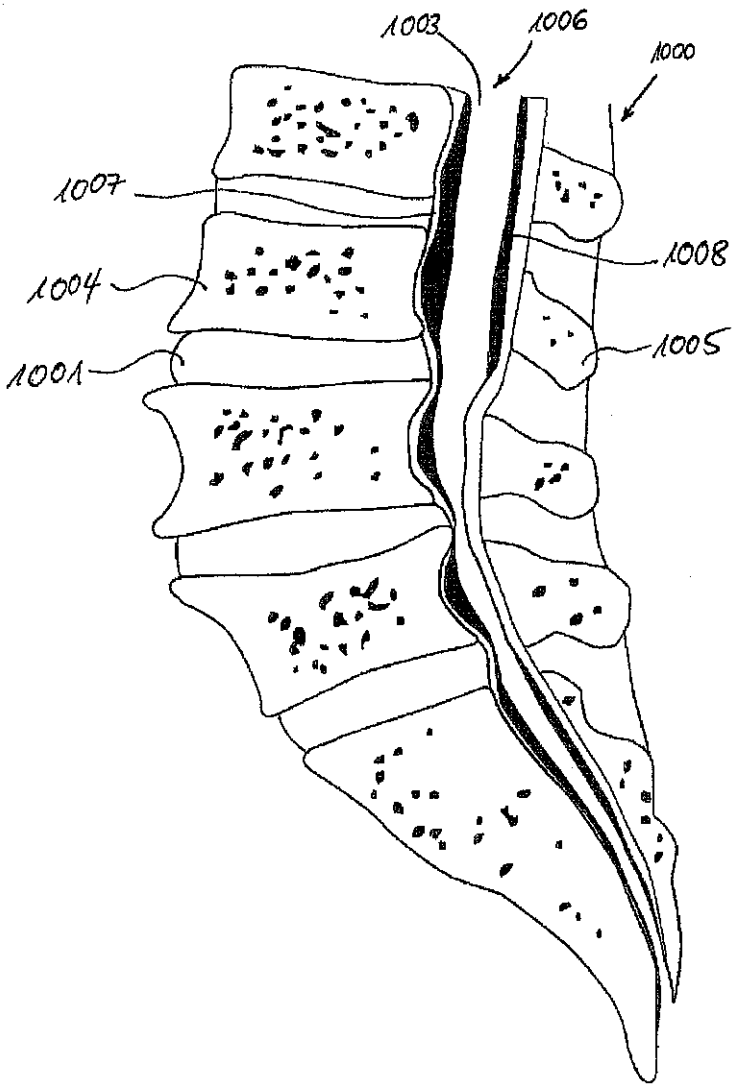



Fig. 1

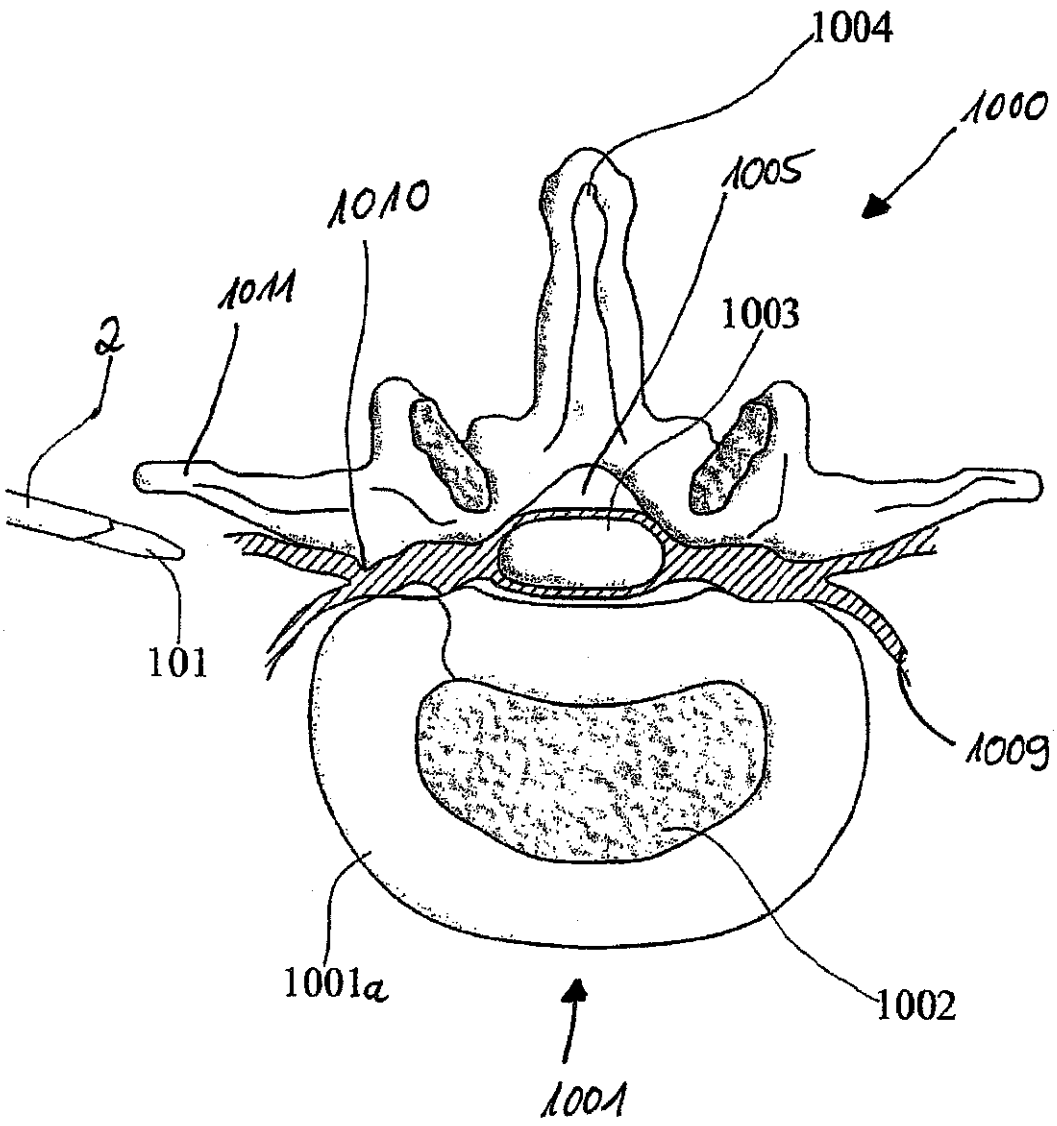



FIG.2

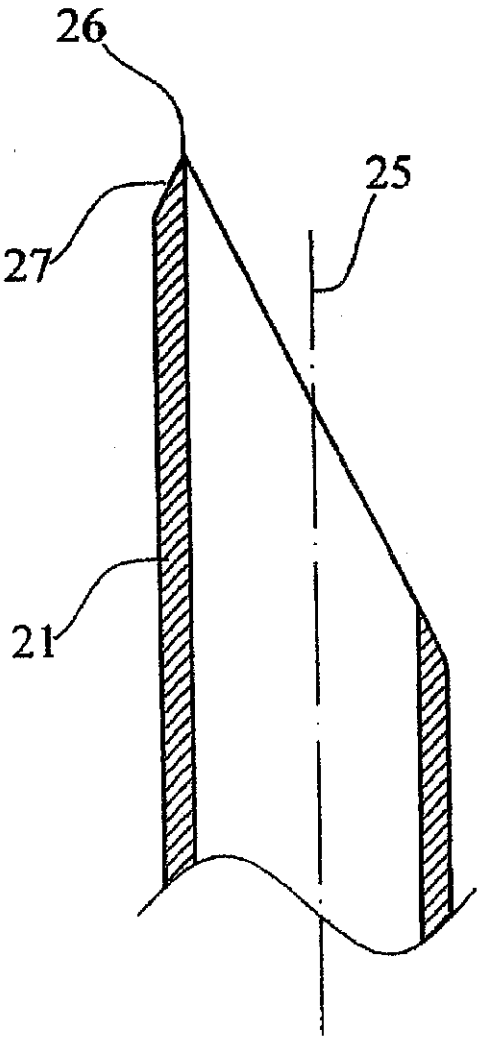



Fig. 3.1

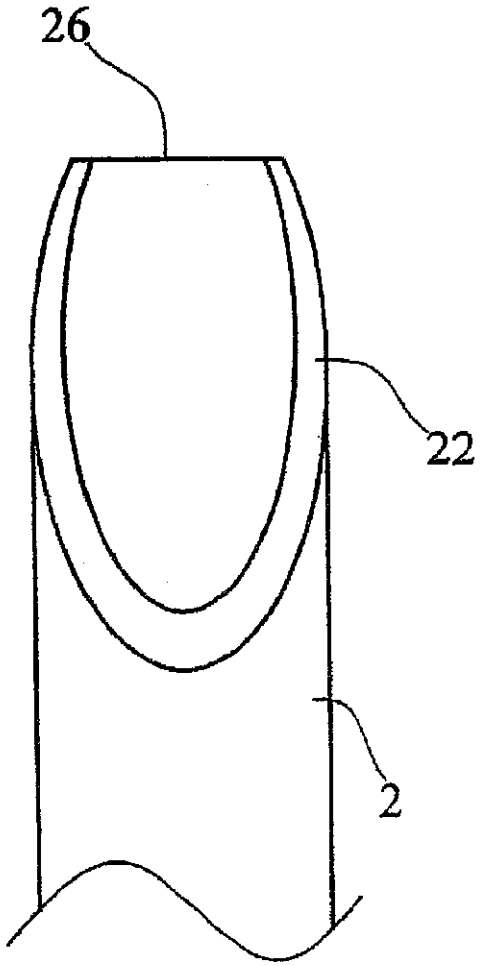



Fig. 3.2

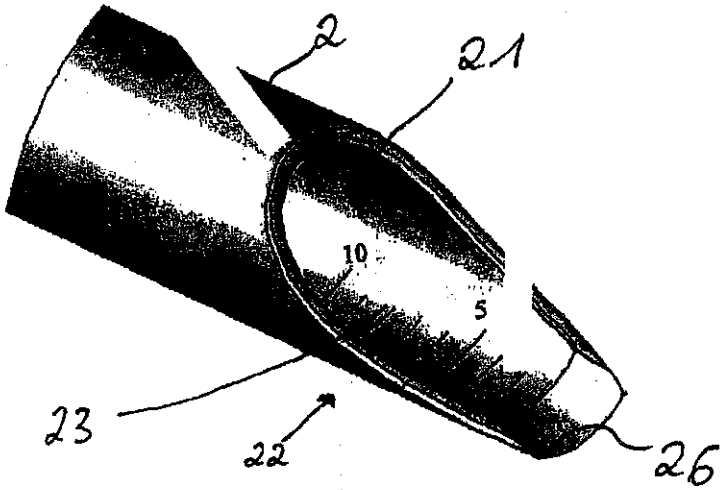



Fig. 3.3

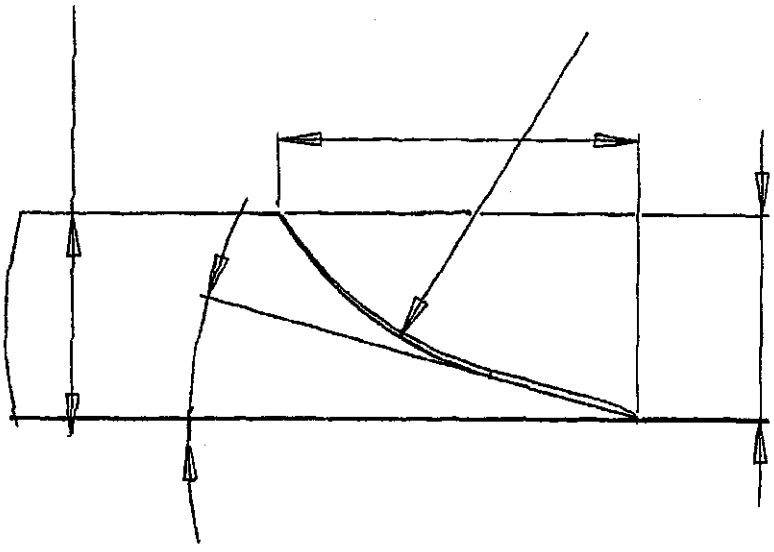


Fig. 3.4

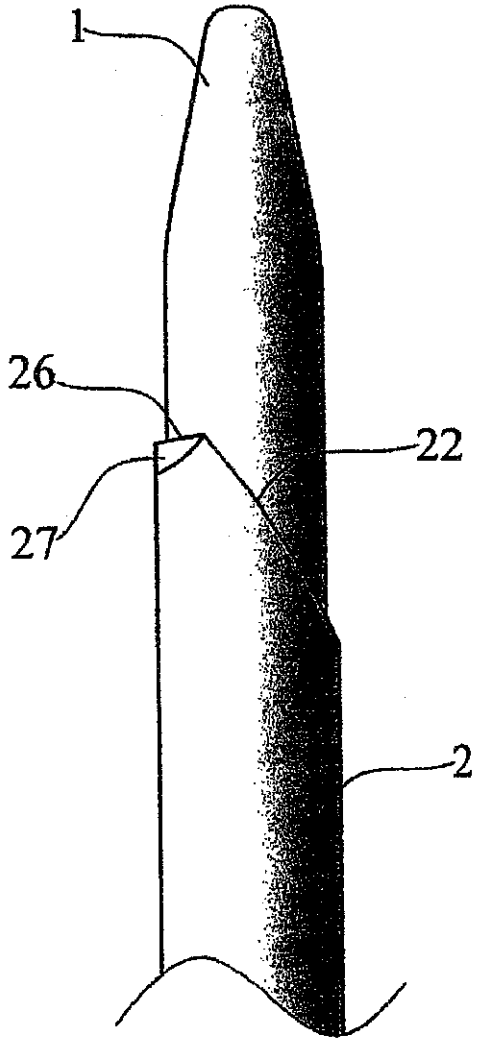



FIG.4

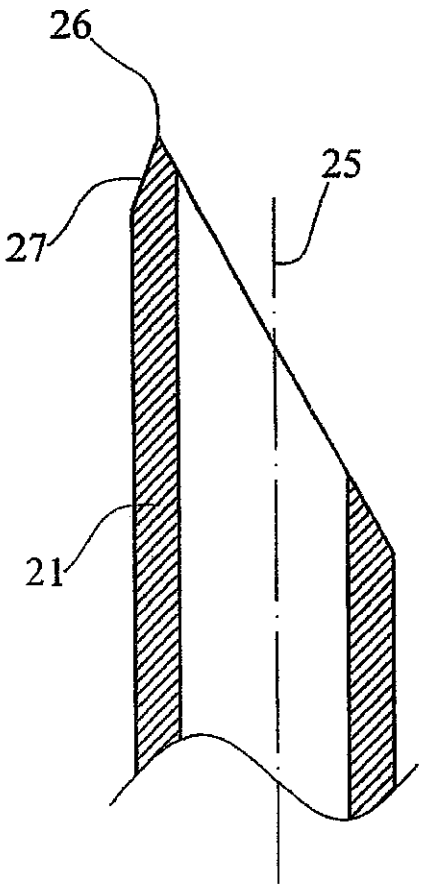



Fig. 5.1

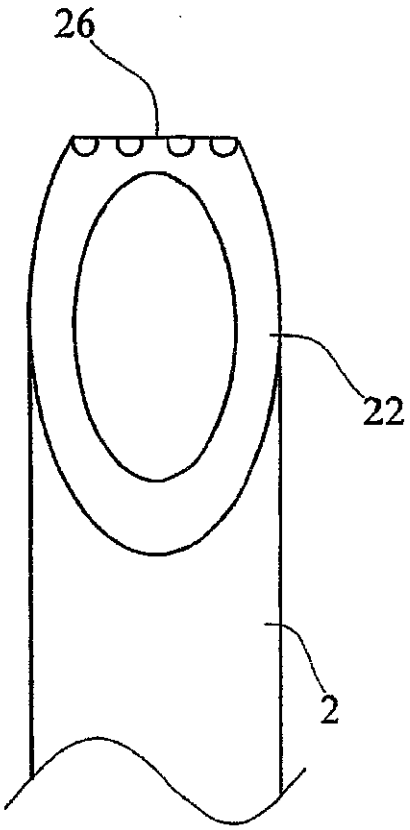



Fig. 5.2

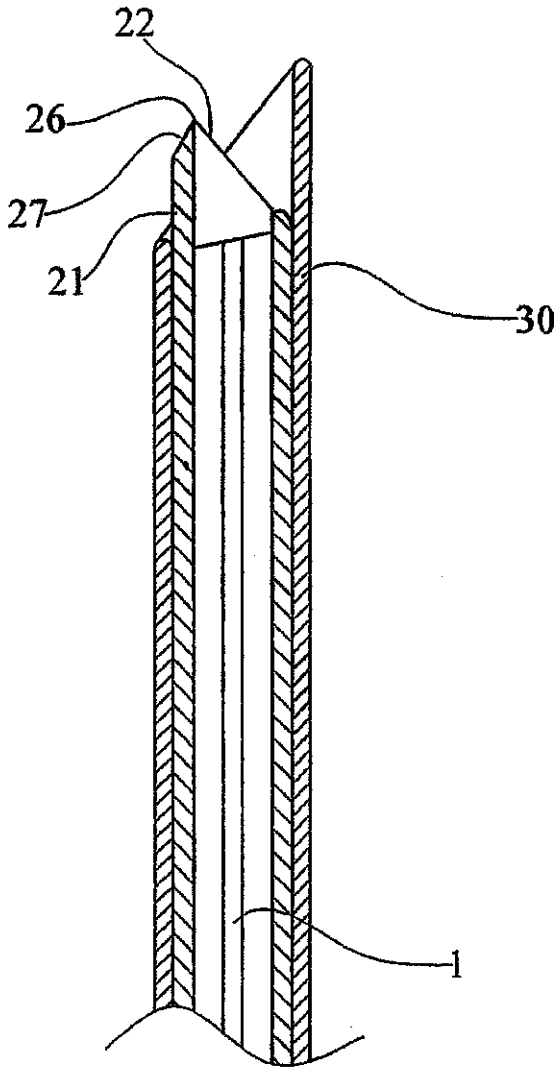



FIG.6

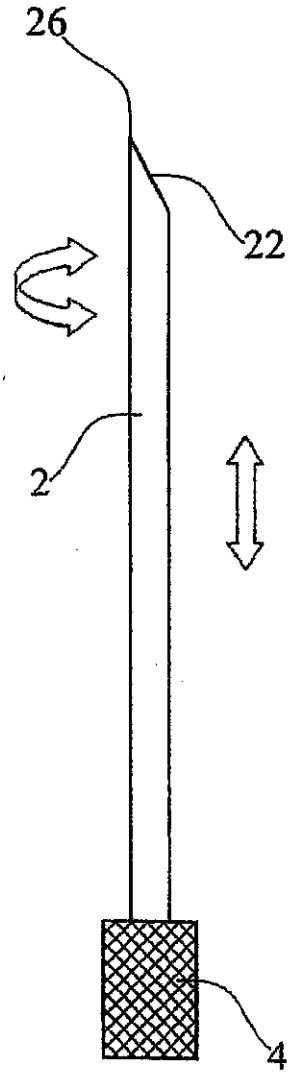



FIG.7

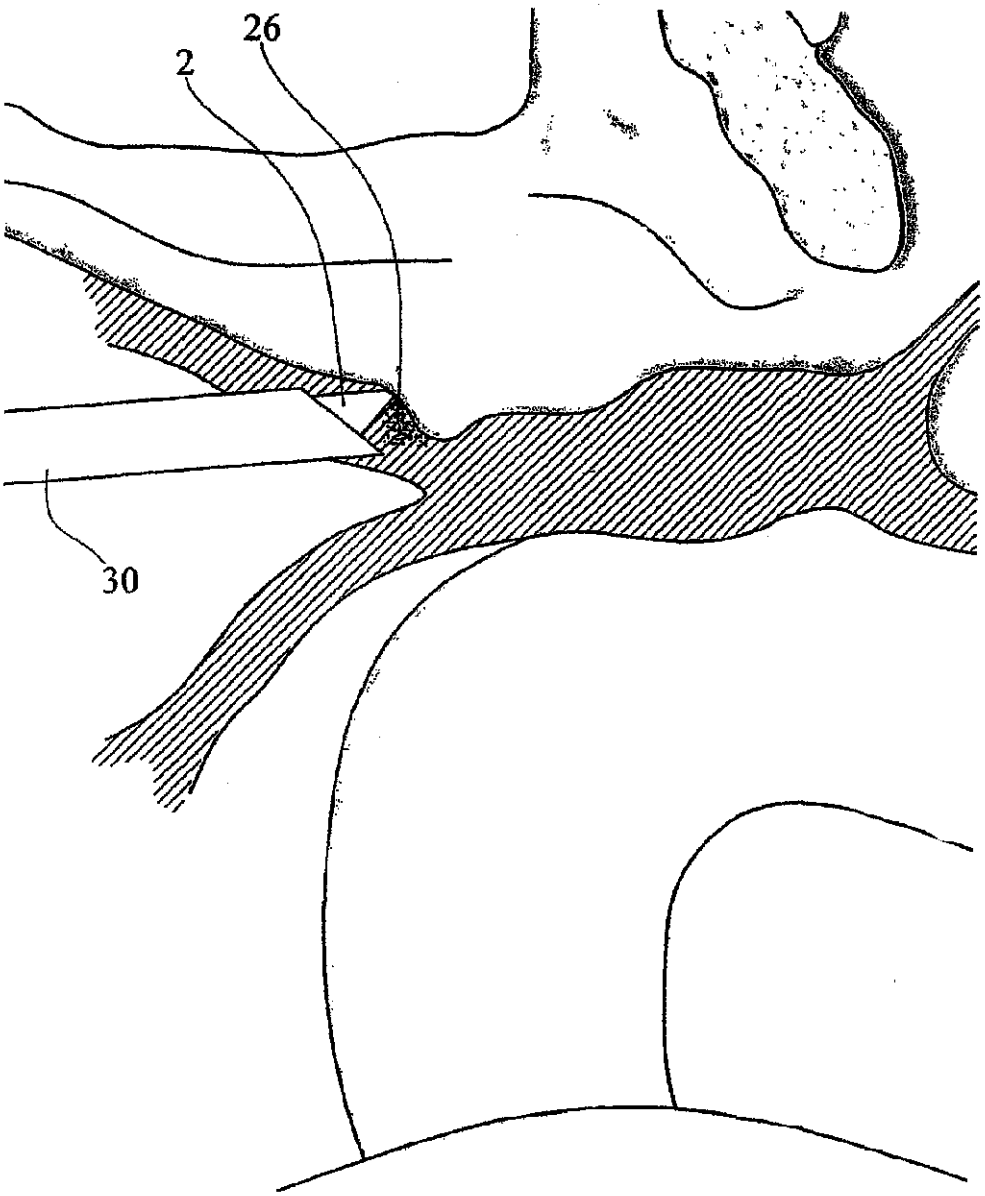



FIG.8

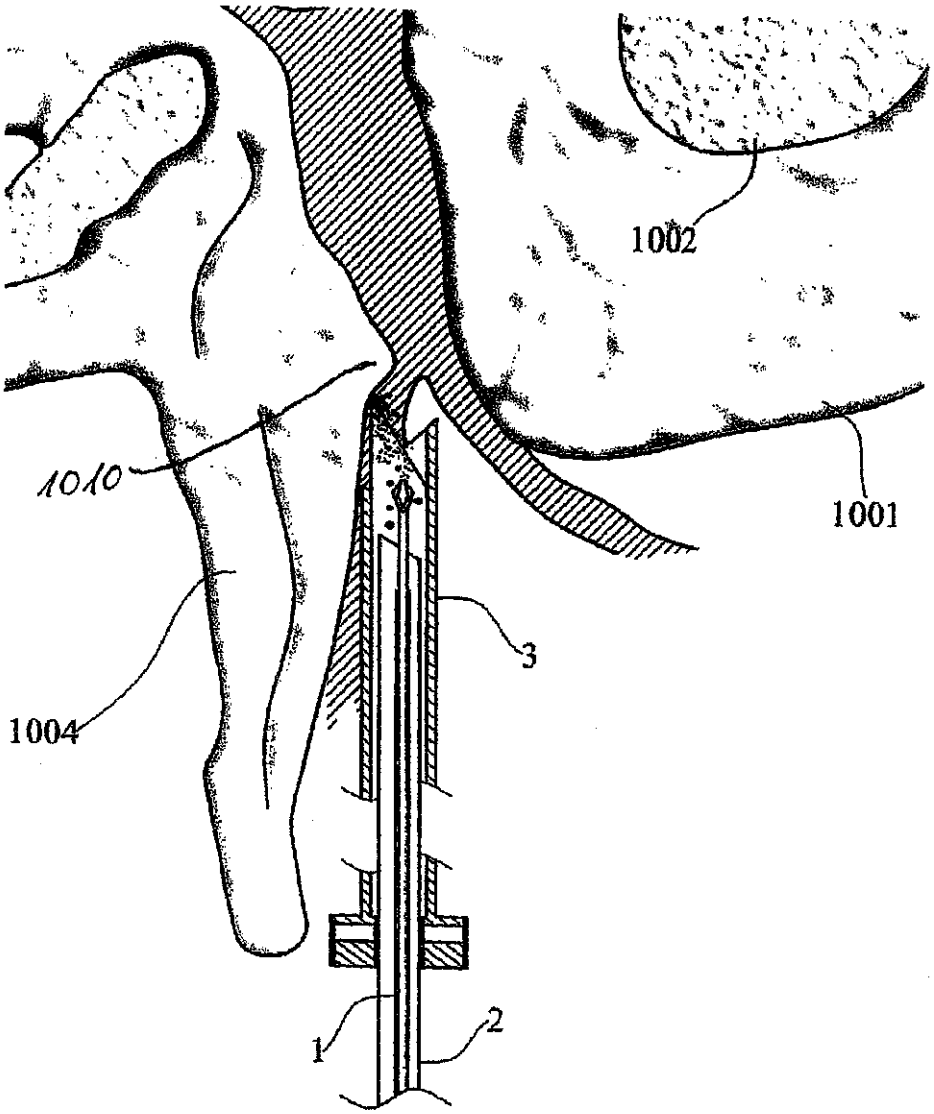



FIG.9

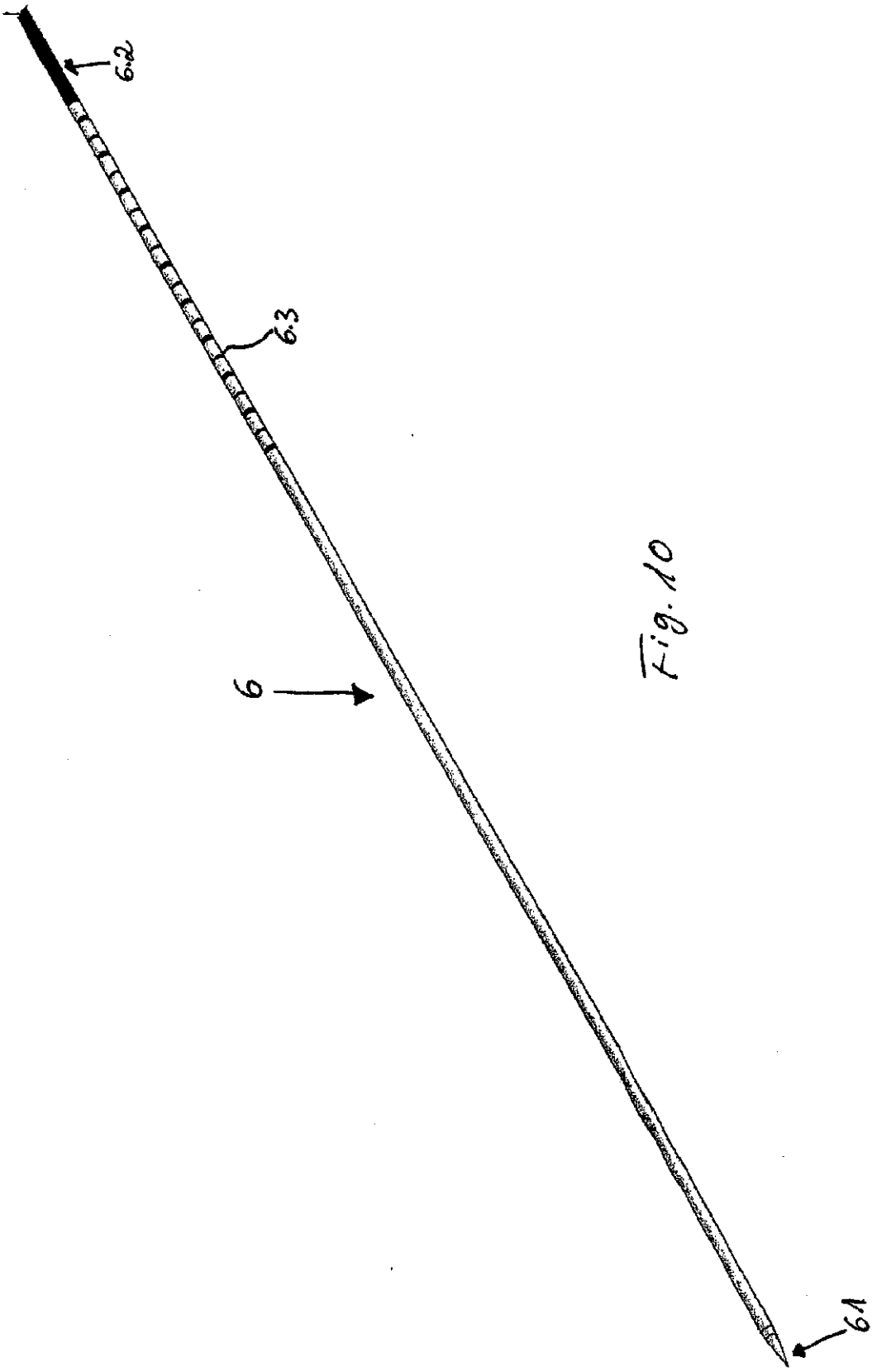



Fig. 10

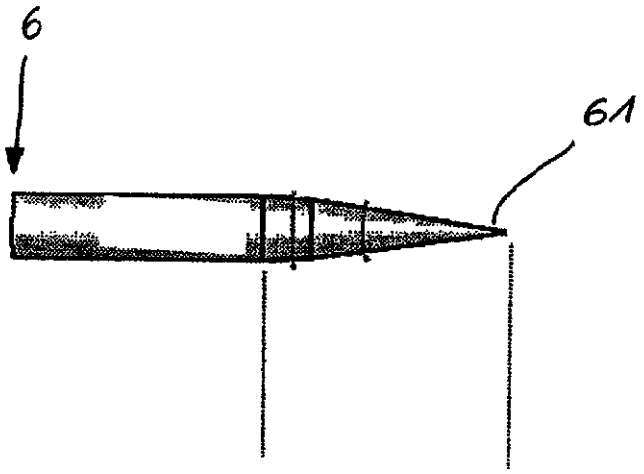



Fig. 10.1

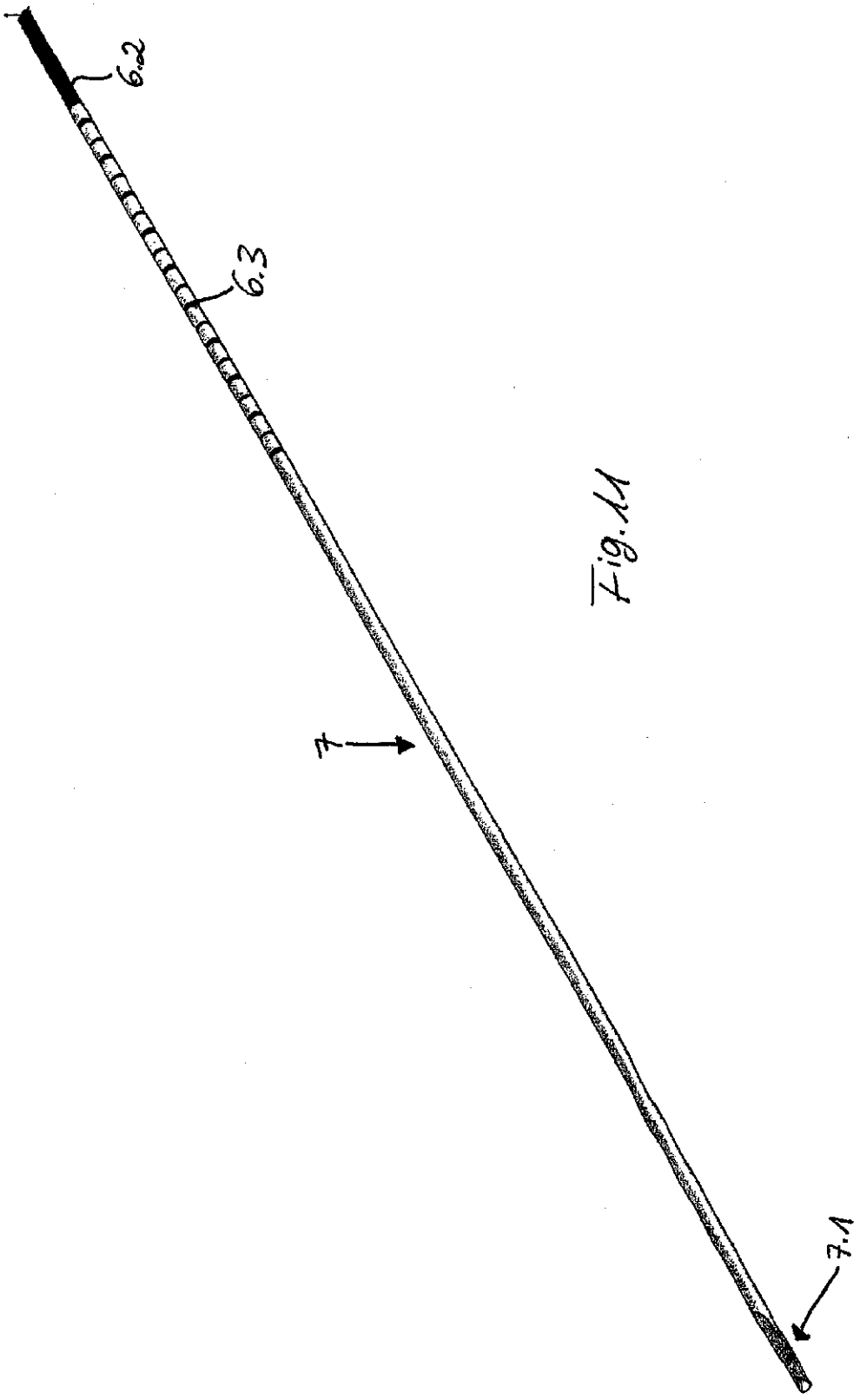



Fig. 11

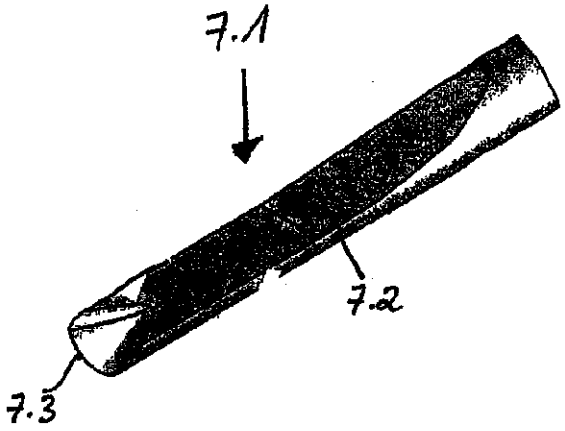



Fig. 11.1

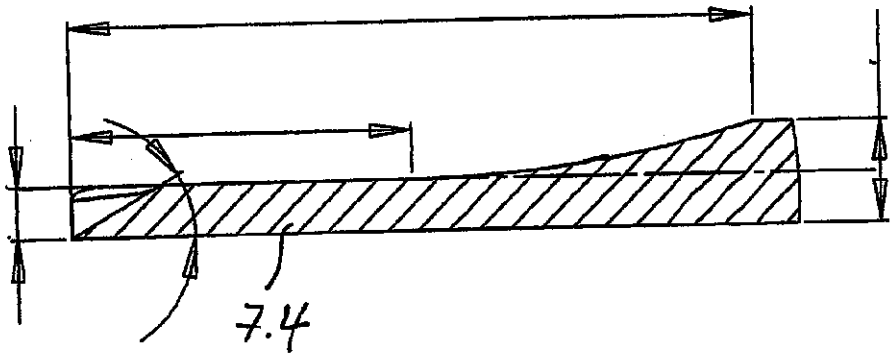



Fig. 11.2

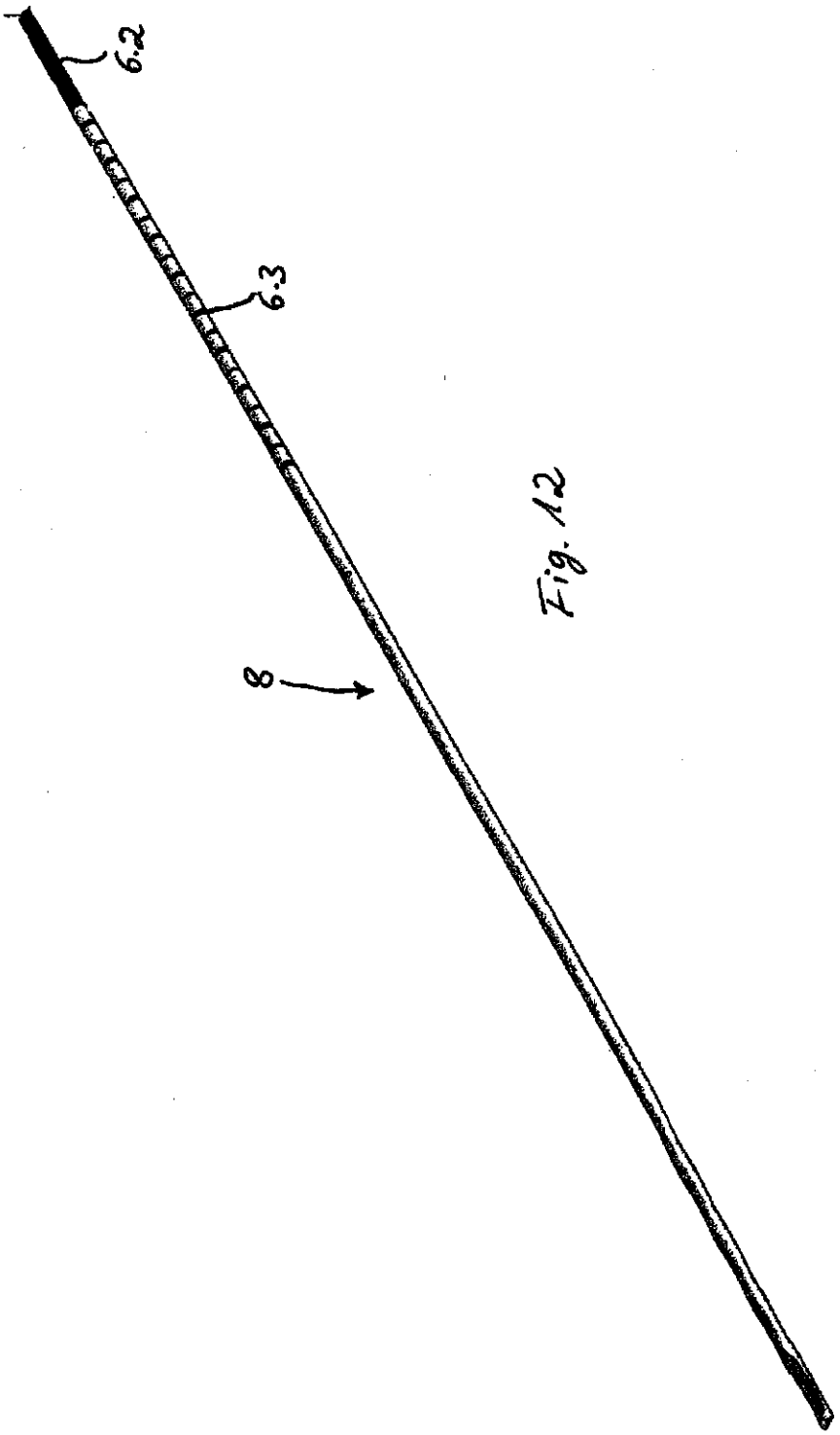



Fig. 12

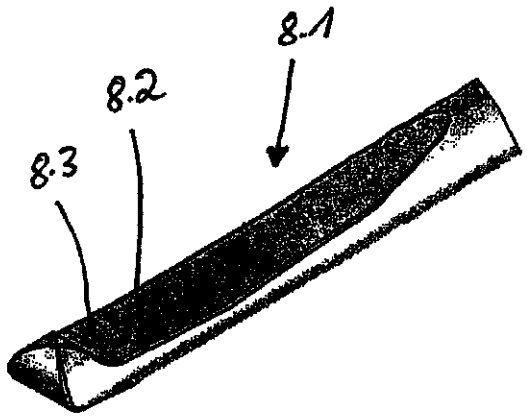



Fig. 12.1

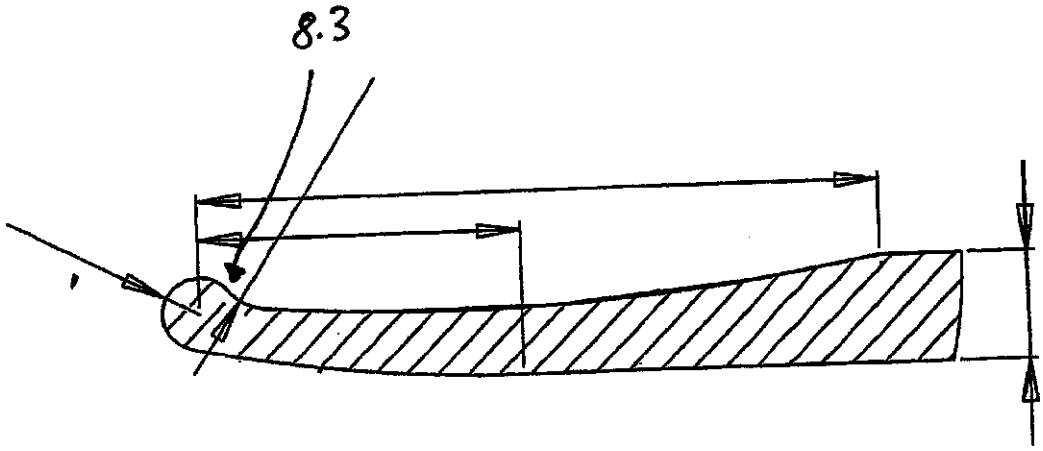



Fig. 12.2

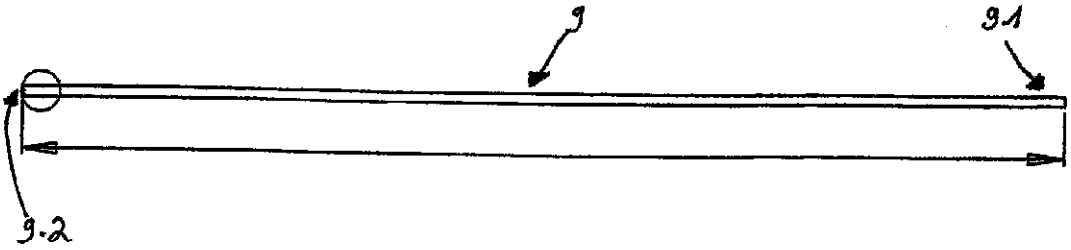



Fig. 13

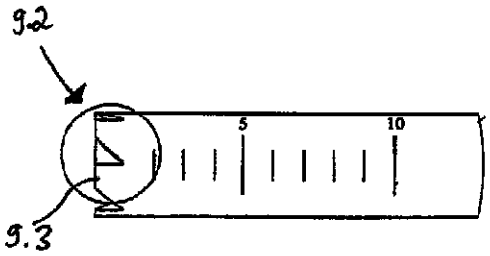



Fig. 13.1

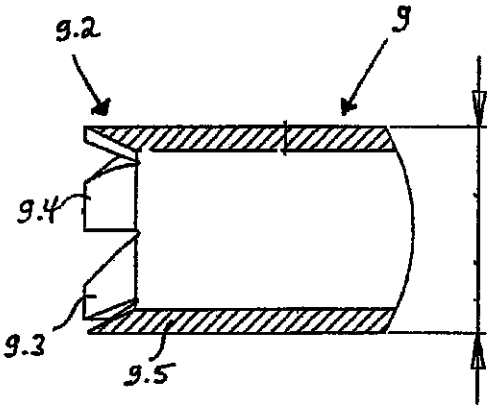



Fig. 13.2

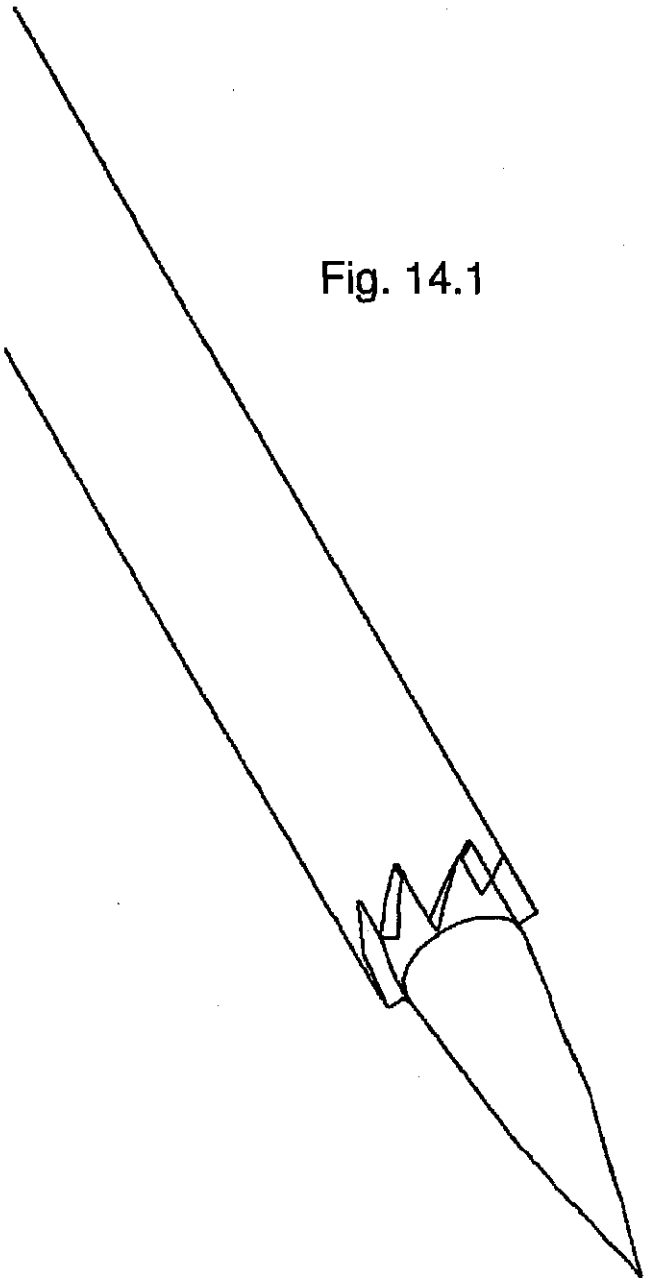


Fig. 14.1

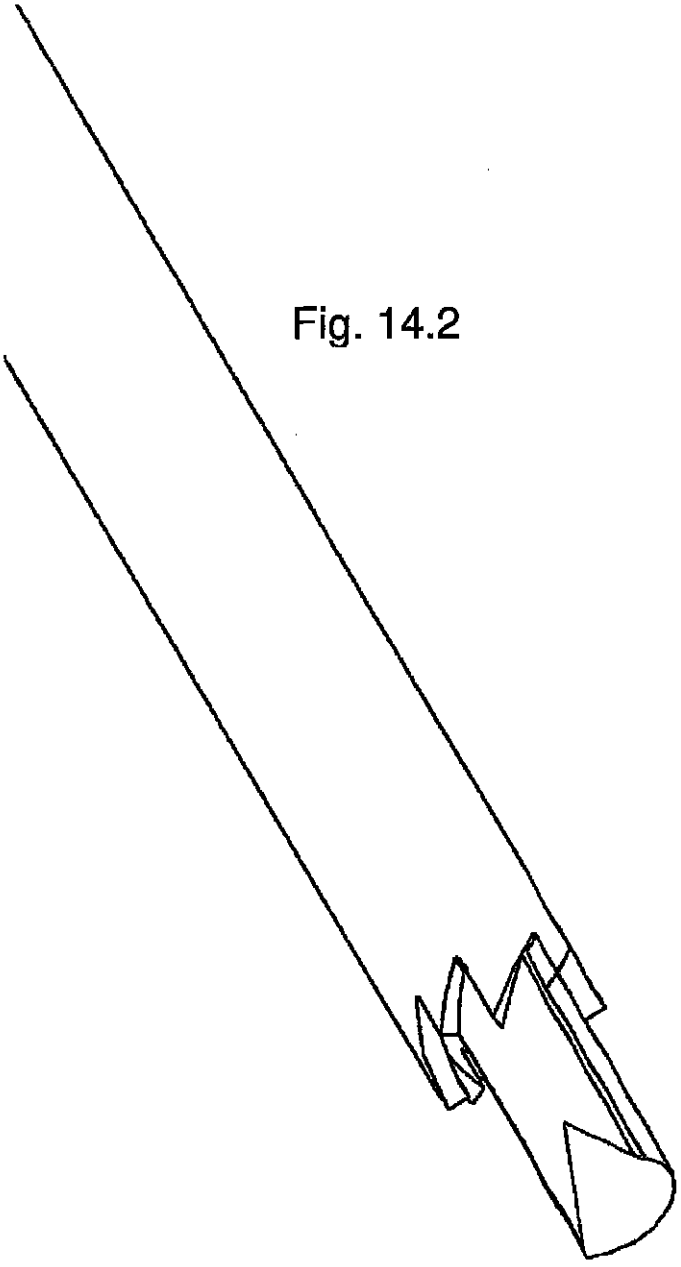
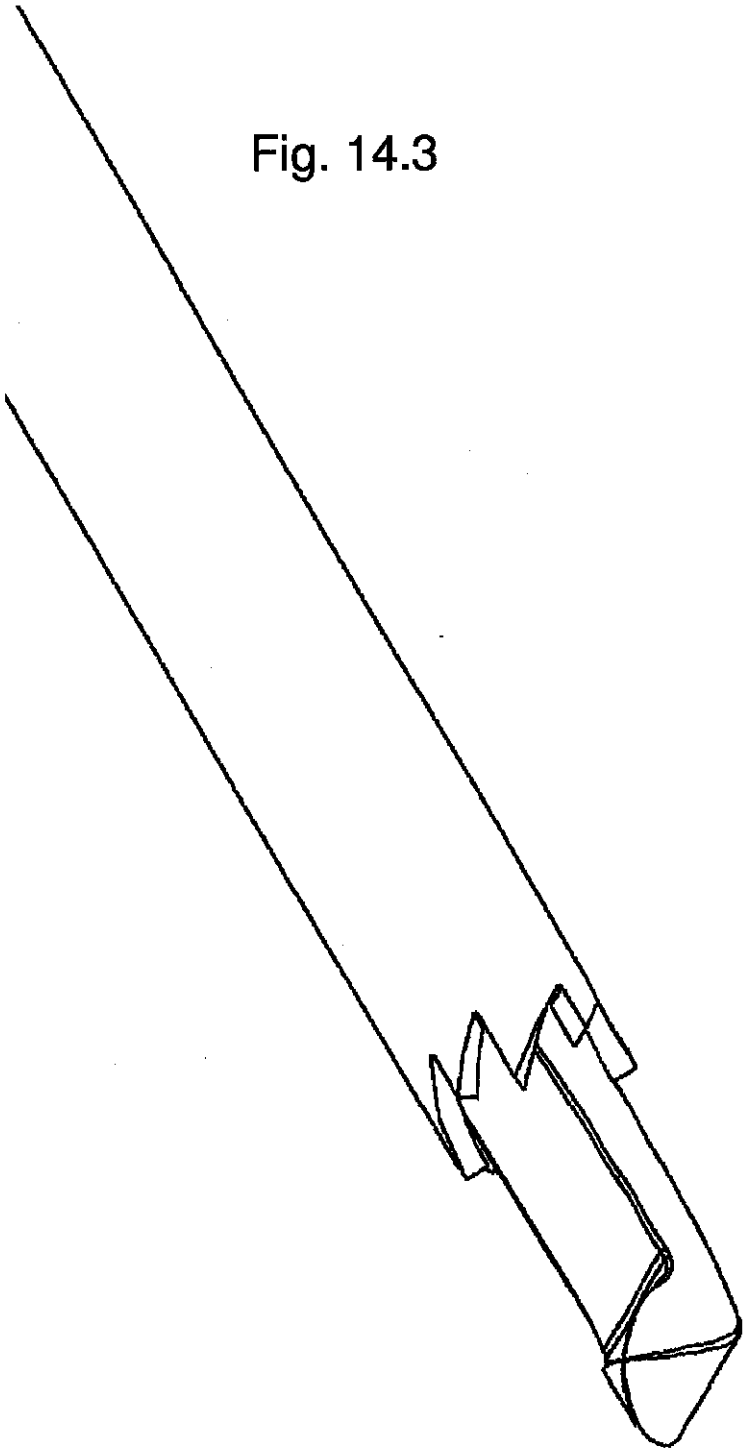


Fig. 14.2

Fig. 14.3



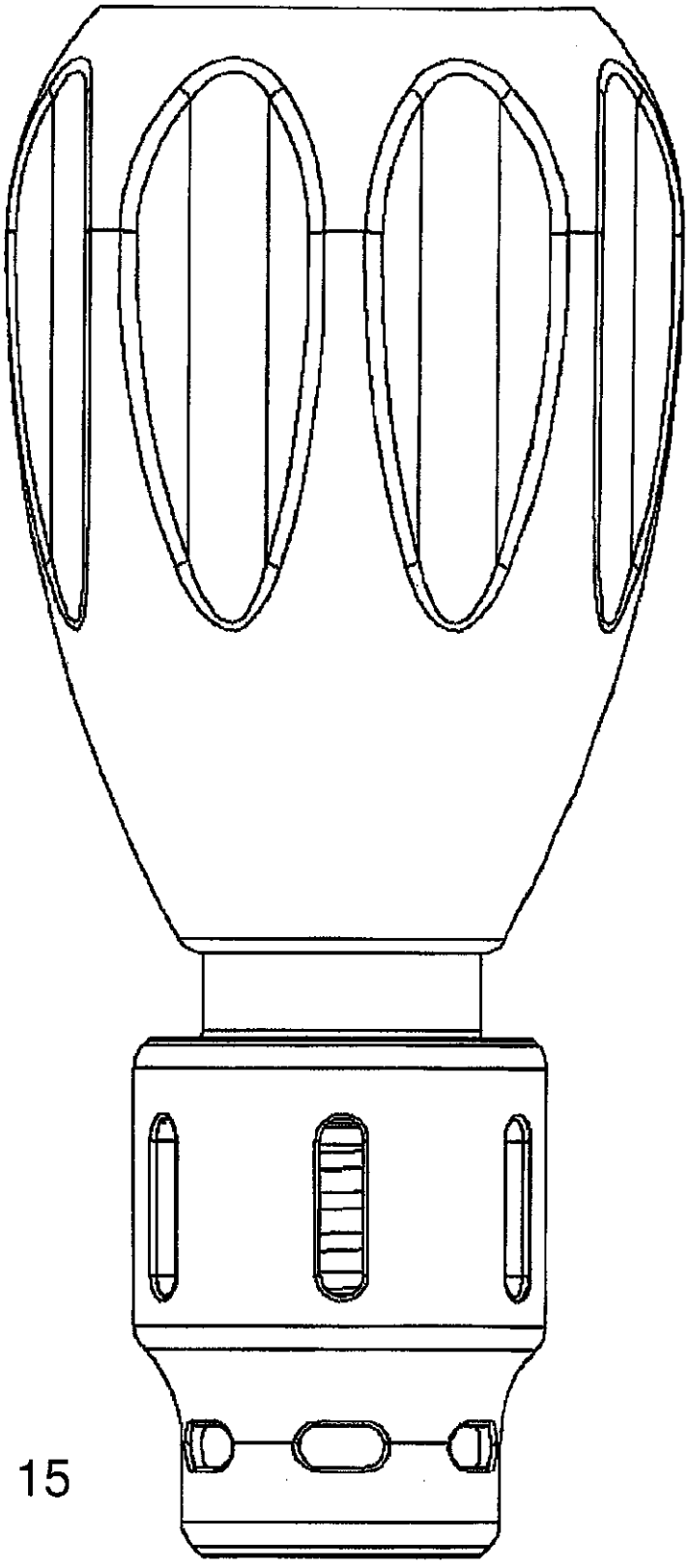


Fig. 15

# DEVICE AND METHOD FOR MINIMALLY INVASIVE SPINAL INTERVENTION

## CROSS REFERENCE TO RELATED APPLICATIONS

This application is a United States National Phase application of International Application PCT/EP2007/010238 and claims the benefit of priority under 35 U.S.C. §119 of Spanish Patent Application ES 2006 03026/4 filed Nov. 27, 2006, the entire contents of which are incorporated herein by reference.

## FIELD OF THE INVENTION

The invention relates to a device for minimally invasive endoscopic intervention in the skeletal region, in particular on the spinal column, having the following elements: a cannula with a distal end having a generally bevelled shape relative to a symmetrical axis of the cutting tool, an optical probe (endoscope) for insertion through the cavity of the cannula; and to a method for minimally invasive intervention in the spinal region, having at least the following steps: at least one rod is brought percutaneously with its distal end at least as far as into the region of the intervention and a hollow tube with bevelled distal end is introduced at least as far as into the region of the intervention, through which hollow tube an endoscope is introduced.

The invention relates in particular to a device for removing tissue during endoscopic interventions, above all for removing bone tissue or connective tissue and other types of tissue.

The invention covers in particular the treatment of spinal stenoses, but also the preparative widening of access channels in relation to endoscopic intervention for treating prolapsed intervertebral discs, the invention not being limited to these possible applications.

## BACKGROUND OF THE INVENTION

Various endoscopic techniques and devices are known for treating a prolapsed intervertebral disc in the spine. Basically, for example, after an incision has been made in the skin of the patient, first of all an elongate element with a tapered rounded tip is inserted (percutaneously), the purpose of which is adaptation of the soft tissue as far as into the immediate vicinity of the damaged disc requiring repair. Once this first elongate element has been introduced, a fine cannula is introduced thereover, the internal diameter of which matches the external diameter of the first elongate element. The external diameter of the cannula may be between 2 mm and 10 mm, with cannulae being used most frequently which have a diameter of approximately 6 mm. This cannula comprises a round cross-section and may have different shapes at its distal end, the distal end generally being bevelled in shape relative to the axis of the cannula, to allow a better view of the working area. After introduction of the cannula the first elongate element is removed, leaving an open access channel to the damaged disc, an optical probe (endoscope) being introduced, which is conformed to this channel and which in turn has channels for pressurized water for cleaning purposes and for sucking out material and working channels for working instruments, such as forceps or the like, for treating and working on the (disc) tissue.

However, the problem may arise that bone tissue or bony growths are present in the working area which hinder the cannula from advancing as far as into the region of the disc to be treated or which have a troublesome effect on the orientation of the cannula with regard to the working area. Often it is necessary, therefore, to use a cutting tool to cut or file away bone tissue so as to obtain access to the site needing treatment.



The techniques which are currently known offer two different solutions to this problem. The first one involves a cutting tool of a size which allows it to be introduced through a working channel of the optical probe. This solution allows the user to remove bone tissue while maintaining visual observation of his actions. However, the problem arises here that the tool has necessarily to have a very reduced diameter (maximum diameter 3.5 mm) and the process of removing bone tissue may take too much time, which is disadvantageous to the patient. The second known solution involves removal of the optical probe and use of a cutting tool with a larger diameter. The difficulty here is that the user has to undertake the intervention without a direct view of the soft tissue present, with the attendant risk of injury to nerve tissue in spiral regions.

In both cases the cutting tool is normally a cylinder, whose distal end is perpendicular to the axis of the cylinder. This distal end normally has a cutting edge of serrated construction. In particular, the diameter of the tool is different for each of the two stated solutions.

The object of the present invention is to propose a device and a method which, while avoiding the above-stated disadvantages, make possible in particular the effective removal of bone tissue in the case of spinal endoscopic intervention and allow visual observation of the intervention at any time by the user.

## SUMMARY OF THE INVENTION

According to the invention, the stated object is achieved with a device of the above-mentioned type which is characterized in that that the cannula takes the form of a hollow cutting tool, in which the most distal region of the distal end comprises a cutting edge, which is incorporated into the edge of the wall of the cutting tool.

Furthermore, to achieve the stated object the invention provides the development of a method of the above type, in that the hollow tube constructed as a cutting instrument with a cutting edge at its front (most distal) end is moved at least percussively against a bone area to be removed.

In a preferred configuration of the device according to the invention, an outer hollow cannula is provided for receiving the cutting tool.

The cutting tool of the device according to the invention may be moved manually (movement of the cutting edge directly by the user's hand), automatically or by a combination of the two ways of proceeding. In the latter two cases, the device has an automatic drive means, so as to allow the cannula-type cutting tool provided with the cutting edge to effect a repeating vibratory movement. The drive may be arranged in a handle, the cutting tool or the corresponding cannula being connected to the drive's output shaft, which moves relative to the handle. Such a vibratory movement may be a to-and-fro movement in the longitudinal direction of the cutting tool and/or a to-and-fro swiveling movement about the axis of the cutting tool, preferably over up to a total of 30°, most preferably less than 12°, i.e. accordingly over 15° or up to 6° relative to a central neutral position. The vibrations contribute to reliable, easy cutting of the bone. The means for generating the movements may be of known type, and may include motors, electromagnetic mechanisms etc.

As is clear from the above, the invention also covers a cutting tool for removing tissue during endoscopic interventions, which may in particular be used as the cutting tool of the

overall device according to the invention. The tool includes an element in the form of a hollow cannula, at the distal end of which there is located a cutting edge and which is distinguished in that the opening of the stated distal end is bevelled in shape relative to a symmetrical axis of the cannula-type element. Because the above-mentioned cutting edge is located at the most remote distal region on the end face of the wall of the cannula-type element, the inner cavity thereof is free, for receiving an optical probe.

So that the cutting tool does not injure any tissue upon introduction, it should preferably comprise a cut profile with a tapered surface, which joins the blade to the outside of the wall of the cannula. Preferably, the blade should be located at least at a radial distance from the inside of the cannula wall which amounts to only a quarter of the radial distance from the outside. It is preferable for the cutting edge to coincide or be aligned with the distal end of the inner side of the cannula wall. In a preferred configuration, the cutting edge is of serrated construction.

Due to the shape of the cutting edge, the cutting tool may be inserted into the human body in a similar manner to already known cannulae, without cutting injuries being caused to the tissue in the area of insertion. In addition, the stated tapered shape allows a correct view of the area to be cut from the inside out by means of an endoscope.

While the above-described tool with bevelled distal end and a cutting edge only at the area projecting furthest is used in particular to sever bony growths in the area where the tools are inserted towards the spinal canal, the invention provides a milling chisel which may be inserted through the endoscope for working on more medial narrowed portions, which milling chisel is in particular of hollow-cylindrical construction and comprises a circular-symmetrical set of teeth at its end-face end.

So that, when working with such a milling tool, guidance of the same is provided and thus the risk of damage to tissue which should not be damaged or indeed to nerves is reduced or eliminated, the invention provides in an extremely preferred development a device which comprises at least one anchoring tool which may be inserted through the endoscope, the device possibly also comprising, as a work kit, two or more such anchoring tools which may optionally be used as alternatives. The anchoring tools are constructed at their distal end in such a way that they may be fixed in particular to the posterior longitudinal ligament of the spinal column. For handling purposes, the anchoring tool is provided at its rear (proximal) end with a connection configuration for non-rotating connection with a handle or the like, the anchoring tool in particular being provided in its rear area, distally relative to the connection configuration, with graduations, in particular in the form of notches extending around part of the circumference of the connecting tool perpendicularly to the longitudinal axis thereof.

In a first preferred configuration, the anchoring tool is an endoawl, the endoawl comprising a sharp distal tip. In another configuration the anchoring tool is an endospatula, the endospatula being provided at its distal end with an end-face cutting edge. Finally, an extremely preferred configuration of the invention is characterized in that the anchoring tool is an endoelevator, the endoelevator in particular comprising in its distal end region firstly a taper and then a thickened portion at its outermost distal end.

The method according to the invention provides, in a preferred development, for the cutting tool to be swivelled over a limited angular range, the cutting tool alternatively or additionally being capable of being moved axially in cycles, i.e. percussively. A preferred further development provides, with regard to the swivel range, that the cutting tool is swivelled over an angular range of up to 30°, preferably of less than 12°. In a further development the method according to the invention provides, for the purposes of the above explanations relating to the removal of more medial stenoses, that an anchoring tool is inserted through the working cavity of an endoscope introduced as far as into the spinal column region and is anchored in the region of the posterior longitudinal ligament, with either an endoawl being introduced as the anchoring tool, which is percussively anchored axially with its sharp tip in the area at the posterior longitudinal ligament or adjacent areas of bone, or an endospatula with flattened distal end being introduced as the working tool and being anchored between the posterior longitudinal ligament and bone by axial application of force or indeed an endoelevator with a thickened portion at the distal end provided with an undercut being introduced as the working tool and being anchored between bone and posterior longitudinal ligament against the latter under tension.

To actually work on the more medial stenosis, a milling chisel is additionally introduced according to the invention over the working tool, acting as a guide tool, and the bone material to be removed is removed therewith by at least one swiveling movement of the milling chisel, the milling chisel likewise being capable of being rotated and/or moved axially in cycles. Drive is preferably achieved by means of a motor.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses, reference is made to the accompanying drawings and descriptive matter in which preferred embodiments of the invention are illustrated.

## BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. **1** shows the lower part of a spine to illustrate the corresponding physical conditions;

FIG. **2** is a schematic representation of a damaged disc (prolapsed intervertebral disc), which exerts pressure on nerve elements, together with an elongate element with round, tapered tip and a cutting tool according to the invention in the vicinity of the region to be operated on;

FIG. **3.1** shows an enlarged vertical section through the distal end region of a cutting tool according to the invention;

FIG. **3.2** is a side view, perpendicular to the axis, of the distal end region of a cutting tool according to the invention;

FIG. **3.3** is an enlarged perspective representation of the distal end region of the cutting tool according to the invention;

FIG. **3.4** is a side view of the distal end region of another embodiment of the cutting tool according to the invention;

FIG. **4** is a side view of a cutting tool according to the invention with an elongate element with rounded, tapered tip (a probe) inside the cutting tool;

FIG. **5.1** shows a longitudinal section through the distal end of a cutting tool according to the invention with modified cutting region;

FIG. **5.2** is a plan view of the distal end of the modified cutting tool according to the invention as in FIG. **5.1**;

FIG. **6** is a schematic representation of a device according to the invention with a cutting tool according to the invention in longitudinal section;

FIG. **7** is a side view of a further configuration of a device according to the invention;

FIGS. **8** & **9** show schematic representations of the device according to the invention ready for use;

FIG. **10** is a perspective side view of an endoawl as a guide element for a milling chisel;

FIG. **10.1** is an enlarged representation of the distal tip of the endoawl of FIG. **10**;

FIG. **11** is a perspective representation of an endospatula sharpened at the distal end as a guide for a milling chisel;

FIG. **11.1** shows an enlarged distal end of the endospatula of FIG. **11**;

FIG. **11.2** shows a longitudinal section through the distal end of an endospatula;

FIG. **12** is a perspective representation of an endoelevator with blunted distal end as a guide for a milling chisel;

FIG. **12.1** is an enlarged representation of the distal end of the endoelevator of FIG. **12**;

FIG. **12.2** is an enlarged longitudinal section through the distal end of the endoelevator;

FIG. **13** is a side view of a milling chisel with hollow shank;

FIG. **13.1** is an enlarged side view of the distal end of the milling chisel of FIG. **13**;

FIG. **13.2** shows an enlarged longitudinal section through the distal end of the milling chisel of FIG. **13**;

FIGS. **14.1-14.3** are representations showing the interaction of endoawl, endospatula and endoelevator with a milling chisel of FIG. **13**; and

FIG. **15** is a side view of a handle for connection to the above-stated tools.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings in particular, FIG. **1** shows in longitudinal section the lower area of a spinal column **1000** with vertebrae **1004** and the spinous process (Processus spinosus) **1005** extending backwards (dorsally) away therefrom, between which—in the cross-section shown—are located the vertebral holes (vertebral foramen) forming the spinal canal **1006** of the spinal column **1000**. Between the vertebrae **1004** there are located the intervertebral discs **1001** with their nucleus **1002** (FIG. **2**) and their ring (annulus) **1001***a*.

The vertebrae are connected together at the front (ventral) side of the spinal canal by the anterior longitudinal ligament **1007** (Ligamentum longitudinale anterius), while the posterior longitudinal ligament (Ligamentum longitudinale posterius) **1008** is located to the rear of the spinal canal **1006**, in front of the spinous processes **1005**, the posterior longitudinal ligament being connected only loosely to the vertebrae but firmly to the discs **1001**. Nerve tissue **1003** extends through the spinal canal **1006**, individual nerves **1009** (FIG. **2**) exiting laterally between the vertebrae **1004**. To the side of the spinal canal **1006** (concealed by the nerve tissue **1003** and therefore not visible in FIG. **1**) there is in each case located a "yellow" ligament (Ligamentum flavum) which is located in each case between two vertebrae and stabilizes the spinal column.

As is visible in particular from FIG. **2**, there is a possibility in particular of minimally invasive access to the spinal canal **1005** at the level of the discs **1001**, for example to remedy prolapsed discs, which press on the nerve tissue **1003** in the spinal canal **1005** and cause pain.

A bony growth **1010** on a transverse process (Processus transversus) **1011** of the vertebra **1004** towards the vertebral body or the disc is visible, which narrows access to the medial region of the spinal canal **1005** and prevents a hollow tube of sufficiently large diameter for introduction of an endoscope from being inserted.

The cutting tool **2** according to the invention is constructed at its distal end for removal of the bony growth **1010**.

To this end, hitherto an elongate guide element was initially introduced, over which, optionally in the context of a dilatation process, one or more cannulae, in particular a cannula with a distal end with generally tapered geometry relative to the axis of symmetry, were introduced, so preventing in particular the entraining of tissue located in the operation region to the region treated. The distal end may for example be flat in shape, but other shapes are also possible and known, provided that the end is more distal at a first part than at a second part, i.e. has a generally oblique shape with regard to the axis of symmetry of the cannula.

The edges, which are defined by the wall of the cannula, are rounded, in order to counteract the risk of injury to tissue during introduction of the cannula.

Working instruments or an optical probe or an endoscope are introduced through the hollow region of the cannula. In the latter case, this is so as to be able to obtain images of the working area. In addition, inlet and outlet channels may be provided in the cannula for rinsing through with pressurized water. This pressurized water is used to remove residues and to obtain a cleaner camera image of the operation region. An endoscope is an apparatus with a substantially cylindrical main body with an optical channel, which optionally comprises a light guide and through which light may exit from the distal end of the apparatus to illuminate the surrounding area and from there an image may enter, which may be observed directly at the proximal end by way of a microscope or indirectly using an image converter and a screen. In the present case of minimally invasive operative intervention, the elongate main body of the endoscope in any case additionally comprises a hollow working channel, through which working instruments may be guided and introduced from the proximal end to the distal end.

FIG. **2** shows introduction of a cutting tool according to the invention or a cutting cannula, as will be described in greater detail below, over an elongate guide element **101** from the side towards the spinal canal **1006**. The elongate element **101** is introduced through an incision in the skin of the patient into his/her body. The tapered round tip serves to push endogenous tissue to the side, so as to allow the introduction of a cannula for the endoscope, without that this causing damage within the body. The cannula has an internal diameter which corresponds roughly to the external diameter of the elongate element **101**. In this way, tissue is prevented from being pushed into an otherwise possible gap between the elongate element **101** and the cannula and severed. Once the cannula has been introduced, the elongate element **1001** is removed, such that the inside of the cannula is hollow. The inside of the cannula is used by the user as a working area and cutting instruments, optical probes (endoscopes), forceps etc. may be introduced. Moreover, working channels may be present inside the probe, in order to create a flow of pressurized aqueous liquid, which serves to keep the endoscope clean, such that it is possible to see the operation region, and may be used to remove residues arising during the intervention. All instruments which are introduced into the cannula are elongate in shape. Thus, for instance, the hitherto known cutting instruments have an elongate cylindrical shape with an oblique, saw blade-shaped end, which simplifies cutting.

The diameter of the cannula is limited for obvious reasons (restriction of tissue expansion and of the incision to be performed). As a consequence of this limitation, the inside of the cannula merely allows the simultaneous introduction of an optical probe with an additional working channel for a cutting tool of very reduced diameter, which may not be very useful in meeting the requirements of cutting bone tissue. In these cases it is necessary to remove the optical probe from the

inside of the cannula and to introduce a non-optical probe, which has a wider working channel for a larger diameter cutting tool. In this case, cutting of bone tissue proceeds blind, i.e. without the possibility of observing the soft tissue, which is clearly very dangerous, since nerve tissue can be irreparably damaged and the success of the intervention depends on the dexterity of the operating surgeon.

To avoid these difficulties, the cannula according to the invention takes the form of a cannula-type cutting tool **2**. This has a distal end **22** bevelled relative to the axis of symmetry **25** of the cannula. The size of the cutting tool **2** allows introduction into the body in the above-described manner and simultaneously allows positioning of an optical probe through the inside thereof, in a similar manner to already known cannulae.

The characteristic feature of the present invention is that the cutting tool **2**, which constitutes the core subject matter of the invention, has a cutting edge **26** at the most distal region of the distal end, i.e. at the end-face edge of the cannula wall **21**.

The fact that the cutting edge **26** is located at the endface edge of the cannula wall results in the cutting tool **2**, which constitutes the subject matter of the invention, being able, like a cannula of the endoscopic systems of known type, to be introduced into the body. Then when an elongate element **101** is introduced, which fills the entire inside, the cutting edge **26** cannot sever the tissue, as is clear from FIG. **4**. On the other hand, the general oblique shape of the distal end of the cutting tool **2** allows a correct view of the region to be cut from the inside of the cannula-type cutting tool **2** out.

In the case of the example shown in FIG. **3**, the cutting edge **26** lies on the inner side of the cannula wall **21**. Moreover, the cutting edge **26** consists of a cut **27** in the cannula wall **21**, which extends obliquely relative to the outside of the wall towards the inside in the region of the distal end **22** of the tool **2** (FIG. **3**, **4**).

FIG. **3.3** shows that a graduation **23** or scale is located on the inside of the extension of the cutting tool **2**, for example by means of etched-in transverse indentations. In addition, the edge of the end-face opening of the cutting tool **2** is rounded apart from in the area of the sharp edge **26** located at the front end face. Finally it is apparent from FIG. **2** that in the embodiment illustrated herein the end face of the cutting tool **2** is not merely bevelled but rather in side view is initially arcuate from the proximal side of the opening and only flattens out obliquely in its distal end region, wherein it here preferably forms an angle of the order of 10 to 20° with the longitudinal axis or side wall. The diameter of a cannula-type cutting tool **2** according to the invention should be greater than 3 mm and preferably lie in the range from 5 to 7 mm.

FIG. **5** shows an alternative configuration of the cutting tool **2**, which constitutes the subject matter of this invention. In this case the cutting edge **26** is serrated and does not coincide with the inside of the cannula wall **21**. However, this tool does not cause cutting injuries to tissue either, if it is introduced in the ways described above.

In the examples illustrated in FIGS. **3.1**, **3.2** and **5.1**, **5.2** the opening of the distal end of the cutting tool **2** is defined by a plane. However, this opening may also assume other forms, such as for example a curved surface (FIG. **3.3**) etc. The cutting tools **2** may have a similar diameter to that of the outer cannulae of the prior art devices, but in particular and advantageously have a somewhat larger diameter, such that endoscopes with larger diameters than hitherto may also be used. In the case of a system according to the present invention, the cutting tool **2** combines the functions of the outer cannula and of the cutting tool. The system according to this invention is completed by an optical probe **1** (endoscope), which is located inside the cannula-type cutting tool **2** with the cutting edge **26** and has a working channel for tools. It is advantageous to use a further, outer, hollow cannula **30** with a diameter which is greater than or equal to that of the cutting tool **2** with cutting edge **26**. This external cannula **30** may be conformed to the cutting tool **2** with cutting edge **26** and correspond with regard to its configuration to known outer cannulae (not in its diameter). By way of this cannula **30** better monitoring over the working area is achieved, e.g. through the pouring in of pressurized fluid through a working channel FIG. **6** shows a device of this type. FIGS. **8** and **9** show schematic representations of the mode of operation. The outer cannula **30** is immobile, while the cutting tool **2** moves in order to cut the bony growth **1010**. Under these conditions, pressurized fluid may for example be rinsed through the working channel, such that the dimensions of the working space through which the pressurized fluid is rinsed do not vary with the movement of the cutting tool **2**.

The invention thus also has the advantage of being able to cut without impairing the working channels of the optical probe. In FIG. **9** endoscopic forceps are inserted through a working channel of the probe **1**. Moreover, as is clear from FIGS. **7** to **9**, the system may have means **4** for allowing alternating movement of the cutting tool **2**, so as in this way to simplify cutting of the bone tissue. Various techniques are available for allowing this type of movement: pneumatic, magnetic, electrical, mechanical systems etc. Therefore, they will not be described in any further detail here. These means may include means of allowing movement lengthways relative to an axis of the cutting tool **2** or an alternating movement about an axis **25** of the tool, preferably with the swiveling movement being restricted to a radius of up to 15°, in particular less than 6° with regard to a neutral position, thus with a total swivel range of 30° or preferably up to 12°.

As far as size is concerned, the cutting tool **2** may have an internal diameter of between 2.7 mm and 7.3 mm, but preferably between 3.2 and 6.1 mm. The length of the cutting tool and the further means may correspond to those of the already known systems.

The method according to the invention thus so far comprises the following:

In the case of a skin incision, first of all at least one rod-shaped tool is introduced. Preferably, a plurality of tubular dilating tools of increasing diameter are introduced one over the other, until finally the cutting tool according to the invention may be introduced. The dilating rods fitting closely inside the same are removed and then an endoscope is introduced through the cutting tool as far as the distal region of the cutting tool, such that the working area of the cutting edge of the cutting tool may be monitored.

Then work with the cutting tool may proceed by rhythmic or cyclic percussion and swiveling to-and-fro, in order to remove a bony growth, a bony protrusion or the like.

In particular, if the restriction actually caused by bone marrow is situated in the entry zone of the introduction channel, as is the case with the narrowed portion **1010** of FIG. **1**, "freehand working", as described above, is possible. However, this is less or no longer applicable where bone material to be removed is more medial and closer to nerve tissue **1003**, since slippage of the sharp edge **26** of the cutting tool **2** may lead to nerve damage. In this case, at least a degree of reliable guidance is needed for cannula-type working tools. It is therefore necessary to anchor guide tools for cannula-type working tools reliably with their distal end in the spinal canal or in material defining the latter.

To this end, the invention firstly provides, in a first configuration according to the invention, an endoawl **6**, as illustrated

in FIG. **10**. The endoawl **6** in FIG. **10** comprises a solid elongate rod with a pointed, sharp distal end **6.1**, a rear or proximal non-circular-symmetrical gripping end **6.2**, on which a handle may be non-rotatably mounted, and a graduation **6.3** likewise arranged in the rear or proximal area produced by lines in the form of indentations arranged at the circumference perpendicularly to the longitudinal axis.

The endoawl **6** has a total length of between 300 mm and 400 mm, preferably 370 mm, a gripping end **6.2** of between 20 mm and 30 mm, preferably 25 mm, a length from the last distal graduation line to the tip of between 200 mm and 300 mm, preferably 250 mm, and a tip length of between 5 mm and 15 mm, preferably 10 mm. The diameter of an endoawl **6** according to the invention is between 2 mm and 3.5 mm, preferably in the range from 2.6 mm to 3 mm. The conical tip **6.1** is subdivided into two portions with a shorter portion, which has a conicity of 6°, and a longer portion with a conicity of 17°, the latter extending over approximately three quarters to four fifths of the total length of the conical tip **6.1**.

The endoawl **6** is anchored to internal material at the posterior longitudinal ligament by axially acting force, such as for example by means of hammers. The endoawl **6** may then serve to guide a milling chisel, as described further below.

Once the entry zone has been widened in the above-described manner, the endoawl **6** is introduced endoscopically with observation, i.e. through the working cavity of an endoscope, and anchored in place.

It is possible that in certain cases anchoring merely by driving in an endoawl **6** with a sharp tip is unsuitable or insufficient.

In this case the invention additionally or alternatively provides an endospatula **7** for anchoring purposes, as illustrated in FIGS. **11** and **11.1**. The endospatula **7** also comprises a solid, rod-type elongate cylindrical body. It is provided with the same gripping end **6.2** and the same graduation **6.3** as the endoawl **6**, for which reason the same reference numerals are also used. However, its distal end region **7.1** is configured markedly differently from the endoawl **6**. As is clear in particular from FIG. **11.1**, the distal end region firstly comprises an arcuate flattened portion **7.2**, which then develops into a sharp end-face edge **7.3**, similar to the edge of the cannula-type cutting tool **2**, wherein this edge is located however on the outside **7.4** of the endospatula **7**, as is apparent in particular from FIG. **11.2**. The rounded flattened area, starting from the cylindrical main part of the endospatula **7**, inclines not in a straight line, but rather in rounded manner with a radius of preferably 35 mm. This is adjoined as far as the distal end of the edge **7.3** of the endospatula **7** by a flat portion, which has approximately the thickness of half the diameter of the main portion of the endospatula **7**, with a length of 7 mm to 15 mm, preferably 10 mm. The bevel to the distal sharp edge **7.3** proceeds at an angle of approximately 25° to 35°, preferably 30° to the longitudinal axis of the endospatula **7**.

As a result of this configuration, it is possible, by means of the edge of the endospatula **7**, preferably with observation, for example in between the posterior longitudinal ligament between the latter and the adjacent bone region, for the distal end of the endospatula **7** to be inserted and anchored there, in order in this way to achieve better, more reliable anchoring than is possible with the endoawl.

Finally, FIGS. **12**, **12.1** and **12.2** show an "endoelevator" **8**, whose distal end may engage behind the posterior longitudinal ligament. Here too, identical parts are again designated with identical reference numerals, i.e. the proximal gripping end **6.2** and the graduation **6.3**. The endoelevator **8** is likewise constructed as a solid hollow shank with a diameter of the order stated above in relation to the endoawl. Its distal end region **8.1** is similar to that of the endospatula **7**, being tapered and flattened down to roughly half the diameter of the solid shank, the taper proceeding by way of a rounded portion with a radius of 60 mm, which is firstly adjoined distally on the tapered side by a flat area **8.2**, on the back of which there is provided convex rounding with a radius of the order of 40 mm about an axis perpendicular to the longitudinal axis of the endoelevator. When viewed in longitudinal section, the front end is thickened and partially circular, such that an undercut is produced at **8.3**. This enables the endoelevator to grip behind the ligaments and also to obtain a certain hold thereon under tension.

As already stated, all of the endoawl, endospatula and endoelevator are fixed in the region of the posterior longitudinal ligaments, in order to serve as guides for a milling chisel, as illustrated in FIGS. **13**, **13.1** and **13.2**.

The milling chisel **9** comprises an extended hollow cylinder of a length which is somewhat less than the length of endoawl, endochisel, and endoelevator. The proximal end **9.1** (not explained here in any more detail) is provided with a coupling configuration, which allows non-rotatable, axially fixed coupling of a handle or rotary drive, like the coupling disclosed in DE 20 2005 016 761.4 U, to which reference is made and which is deemed to be part of the disclosure of the present application.

The distal end **9.2** is provided with teeth **9.3**, the teeth tapering radially to a point, but over the circumference having a finite direction of extension, i.e. comprising a cutting edge **9.4**. The front tooth flank is axially parallel, while the rear tooth flank forms an angle with the axis of the order of 40° to 50°, preferably 45°. The cutting edge **9.4** is located on the outer circumference of the shell **9.5** of the milling chisel **9**.

In addition, on the outside of the shell **9.5** of the milling chisel **9** in the distal end region there is located a graduation, once again formed of indentations or notches extending perpendicularly to the axis in the circumferential direction, which, when the milling chisel **9** is inserted through the working cavity of an endoscope into the working area thereof, may be seen and observed by way of the lateral viewing optics at the distal end of the endoscope.

FIGS. **14.1** to **14.3** show the interaction of a hollow-cylindrical milling chisel **9** with an endoawl **6**, an endospatula **7** or an endoelevator **8**, which in each case extend through the cavity of the milling chisel.

Finally, FIG. **15** is a schematic representation of a handle with a drive inside it and a coupling corresponding to DE 20 2005 016 761.4 U.

The further procedure using endoawl **6**, endospatula **7** or endoelevator **8** and milling chisel **9**, once the endoscope has been introduced in the above-described manner, is as follows:

One of the tools **6**, **7** or **8** is advanced through the working channel of the endoscope extending through the cutting tool **2** as far as the longitudinal ligament at the level of the operation area and anchored there in the manner described, either by pushing in or squeezing between longitudinal ligament and bone material or by hooking behind the longitudinal ligament.

Then the milling chisel **9** is pushed through the working channel of the endoscope over the tool **6**, **7** or **8** and, when it reaches its working or operation region, is set in rotation, such that material in the way of the teeth, such as bony growths or ligament cartilaginification, which press on nerves, may be removed. The internal diameter of the milling chisel **9** is here somewhat greater than the external diameter of the corresponding tool **6**, **7** or **8**, such that the milling chisel **9** is guided

thereby but nevertheless slight lateral mobility is possible and therefore the operating surgeon is provided with a certain degree of working freedom.

While specific embodiments of the invention have been described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.

The invention claimed is:

1. A device for endoscopic intervention in the skeletal region, in particular on the spinal column, the device comprising:

a cutting tool comprising an element in the form of a hollow cannula, said hollow cannula comprising a cutting edge at a distal end thereof, wherein said distal end forms only one face defining an opening, said one face and said opening being generally bevelled in shape relative to a longitudinal axis of symmetry of the element, said cannula comprising a cavity, said opening extending over an entire cross section of said cavity, said cutting edge extending predominantly in a direction perpendicular to said longitudinal axis of said element;

an optical probe (endoscope) moveably mounted in said cavity for insertion through the cavity of the cannula and out of said opening at said distal end;

a means for moving the cutting tool relative to said optical probe, said means for moving the cutting tool brings about a cyclic movement in the longitudinal direction of the cutting tool.

2. A device according to claim 1, wherein the cutting edge is joined to the outside of the wall of the cutting tool via a tapered surface.

3. A device according to claim 1, wherein the radial distance between the cutting edge and the inside of the wall of the cutting tool amounts to at most a quarter of the distance between the cutting edge and the outer surface of the wall.

4. A device according to claim 3, wherein the cutting edge coincides with the end of the inside of the wall of the cutting tool.

5. A device according to claim 1, further comprising an outer hollow cannula for receiving the cutting tool.

6. A device according to claim 1, wherein the means for moving the cutting tool brings about a cyclic swiveling movement about a longitudinal axis of symmetry of the cutting tool.

7. A device according to claim 6, wherein the means for moving the cutting tool brings about a cyclic movement about a longitudinal axis of symmetry of the cutting tool over a swivel radius of in each case up to 15°, preferably less than in each case 6° with regard to a neutral position.

8. A device according to claim 1, wherein the cavity of the cutting tool has an internal diameter of between 2.7 mm and 7.3 mm.

9. A device according to claim 1, wherein the cutting edge is of serrated construction.

10. A device according to claim 1, further comprising a milling chisel which may be inserted through the endoscope.

11. A device according to claim 10, wherein the milling chisel is of hollow-cylindrical construction.

12. A device according to claim 1, further comprising at least one anchoring tool which may be inserted through the endoscope.

13. A device according to claim 12, wherein the anchoring tool may be fixed with its distal end to the posterior longitudinal spinal ligament.

14. A device according to claim 12, wherein the anchoring tool is provided at its rear (proximal) end with a connection configuration for non-rotatable connection with a handle or the like.

15. A device according to claim 12, wherein the anchoring tool is provided in its rear area distally of the connection configuration with graduations, in particular in the form of notches extending around part of the circumference of the connection tool perpendicularly to the longitudinal axis thereof.

16. A device according to claim 12, wherein the anchoring tool is an endoawl.

17. A device according to claim 16, wherein the endoawl comprises a sharp distal tip.

18. A device according to claim 12, wherein the anchoring tool is an endospatula.

19. A device according to claim 18, wherein the endospatula is provided at its distal end with an end-face cutting edge.

20. A device according to claim 12, wherein the anchoring tool is an endoelevator.

21. A device according to claim 20, wherein the endoelevator comprises in its distal end region firstly a taper and then a thickened portion at its outermost distal end.

22. A device according to claim 12, further comprising a handle connectable to the anchoring tool.

23. A device according to claim 10, further comprising a drive, preferably a rotary drive, in particular a rotary drive with chiselling action for the milling chisel.

24. A device according to claim 10, further comprising at least two of the following anchoring tools: endoawl, endospatula and endoelevator.

25. A device according to claim 1, wherein the radial distance between the cutting edge and the inside of the wall of the cutting tool amounts to at most a quarter of the distance between the cutting edge and the outer surface of the wall.

26. A device according to claim 1, wherein the cutting edge coincides with the end of the inside of the wall of the cutting tool.

27. A device according to claim 1, wherein the cavity of the cutting tool has an internal diameter of between 3.2 mm and 6.1 mm.

28. A device according to claim 10, wherein the cutting edge is of serrated construction.

29. A method for minimally invasive intervention in the region of the spinal column, the method comprising at least the following steps:

providing a cutting tool comprising an element in the form of a hollow cannula, said hollow cannula comprising a cutting edge at a distal end thereof, said distal end defining a single opening, said opening at said distal end is generally bevelled in shape relative to a longitudinal axis of symmetry of the element, said cannula comprising a cavity, said single opening extending over an entire cross section of said cavity, said cutting edge extending predominantly in a direction perpendicular to said longitudinal axis of said element;

at least one rod is brought percutaneously with its distal end at least as far as into the intervention region;

introducing said hollow cannula at least as far as into the intervention region around an outside of said rod, and by movement relative to said rod;

introducing an endoscope movably through the hollow cannula;

moving said cannula to have said cutting edge perform cutting of the intervention area, said moving and said

cutting being performed when said cannula is around said outside of said one of said rod and said endoscope.

**30**. A method according to claim **29**, wherein the cutting tool is swivelled over a limited angular range.

**31**. A method according to claim **30**, wherein the cutting tool is swivelled over an angular range of up to 30°, preferably of less than 12°.

**32**. A method according to claim **29**, wherein an anchoring tool is inserted through the working cavity of an endoscope introduced as far as into the spinal column region and is anchored in the region of the posterior longitudinal ligament.

**33**. A method according to claim **32**, wherein an endoawl is introduced as the anchoring tool and is percussively anchored axially with its sharp tip in the area on the posterior longitudinal ligament or adjacent areas of bone.

**34**. A method according to claim **32**, wherein an endospatula with flattened distal end is introduced as the anchoring and is anchored between the posterior longitudinal ligament and bone by axial application of force.

**35**. A method according to claim **32**, wherein an endoelevator with a thickened portion at the distal end provided with an undercut is introduced as the anchoring tool and is anchored between bone and the posterior longitudinal ligament against the latter under tension.

**36**. A method according to claim **32**, wherein a milling chisel is introduced over the anchoring tool, acting as guide tool, and the bone material to be removed is removed therewith by at least one swivelling movement of the milling chisel.

**37**. A method according to claim **36**, wherein the milling chisel is rotated.

**38**. A method according to claim **36**, wherein the milling chisel is moved axially in cycles.

**39**. A method according to claim **36**, wherein the milling chisel is moved by a motor.

**40**. A device in accordance with claim **1**, wherein:

said cutting edge extends in a circumferential direction of said longitudinal axis of said hollow cannula.

**41**. A device in accordance with claim **1**, wherein:

said direction of said cutting edge is arranged to not intersect said longitudinal axis.

**42**. A device in accordance with claim **1**, wherein:

said distal end forms only one said opening which is in communication with said cavity.

**43**. A device in accordance with claim **42**, wherein:

said cutting edge is arranged at farthest distal position of said hollow cannula.

**44**. A device in accordance with claim **43**, wherein:

said hollow cannula has an annular wall that surrounds said cavity, said cutting edge being formed in said annular wall, said annular wall having a radially inside surface and a radially outside surface;

said cutting edge is positioned at said annular wall radially spaced from said outside surface of said annular wall.

**45**. A device in accordance with claim **44**, wherein:

a radial distance between said cutting edge and said inside surface is less than or equal to a quarter of a radial distance between said cutting edge and said outer surface of said annular wall.

**46**. A device for endoscopic intervention in the skeletal region, in particular on the spinal column, the device comprising:

a cutting tool comprising an element in the form of a hollow cannula, said hollow cannula comprising a cutting edge at a distal end thereof, wherein said distal end forms only one face defining an opening, said one face and said opening being generally bevelled in shape relative to a longitudinal axis of symmetry of said element, said cannula comprising a cavity, said opening extending over an entire cross section of said cavity, said cutting edge extending predominantly in a direction perpendicular to said longitudinal axis of said element;

an optical probe (endoscope) moveably mounted in said cavity for insertion through said cavity of said cannula and out of said opening at said distal end; and

a means for moving said cutting tool relative to said optical probe, said means for moving said cutting tool brings about a cyclic swivelling movement about a longitudinal axis of symmetry of said cutting tool.

**47**. A device according to claim **46**, wherein the cutting edge is joined to the outside of the wall of the cutting tool via a tapered surface.

**48**. A device according to claim **46**, wherein the radial distance between the cutting edge and the inside of the wall of the cutting tool amounts to at most a quarter of the distance between the cutting edge and the outer surface of the wall.

**49**. A device according to claim **48**, wherein the cutting edge coincides with the end of the inside of the wall of the cutting tool.

**50**. A device according to claim **46**, further comprising an outer hollow cannula for receiving the cutting tool.

**51**. A device according to claim **46**, wherein the means for moving the cutting tool brings about a cyclic movement about a longitudinal axis of symmetry of the cutting tool over a swivel radius of in each case up to 15°, preferably less than in each case 6° with regard to a neutral position.

**52**. A device according to claim **46**, wherein the cavity of the cutting tool has an internal diameter of between 2.7 mm and 7.3 mm.

**53**. A device according to claim **46**, wherein the cutting edge is of serrated construction.

**54**. A device according to claim **46**, further comprising a milling chisel which may be inserted through the endoscope.

**55**. A device according to claim **54**, wherein the milling chisel is of hollow-cylindrical construction.

**56**. A device according to claim **46**, further comprising at least one anchoring tool which may be inserted through the endoscope.

**57**. A device according to claim **56**, wherein the anchoring tool may be fixed with its distal end to the posterior longitudinal spinal ligament.

**58**. A device according to claim **56**, wherein the anchoring tool is provided at its rear (proximal) end with a connection configuration for non-rotatable connection with a handle or the like.

**59**. A device according to claim **56**, wherein the anchoring tool is provided in its rear area distally of the connection configuration with graduations, in particular in the form of notches extending around part of the circumference of the connection tool perpendicularly to the longitudinal axis thereof.

**60**. A device according to claim **56**, wherein the anchoring tool is an endoawl.

**61**. A device according to claim **60**, wherein the endoawl comprises a sharp distal tip.

**62**. A device according to claim **56**, wherein the anchoring tool is an endospatula.

**63**. A device according to claim **62**, wherein the endospatula is provided at its distal end with an end-face cutting edge.

**64**. A device according to claim **56**, wherein the anchoring tool is an endoelevator.

65. A device according to claim 64, wherein the endoelevator comprises in its distal end region firstly a taper and then a thickened portion at its outermost distal end.

66. A device according to claim 56, further comprising a handle connectable to the anchoring tool.

67. A device according to claim 54, further comprising a drive, preferably a rotary drive, in particular a rotary drive with chiselling action for the milling chisel.

68. A device according to claim 54, further comprising at least two of the following anchoring tools: endoawl, endospatula and endoelevator.

69. A device according to claim 46, wherein the radial distance between the cutting edge and the inside of the wall of the cutting tool amounts to at most a quarter of the distance between the cutting edge and the outer surface of the wall.

70. A device according to claim 46, wherein the cutting edge coincides with the end of the inside of the wall of the cutting tool.

71. A device according to claim 46, wherein the cavity of the cutting tool has an internal diameter of between 3.2 mm and 6.1 mm.

72. A device according to claim 54, wherein the cutting edge is of serrated construction.

73. A device according to claim 46, wherein:
said cutting edge extends in a circumferential direction of said longitudinal axis of said hollow cannula.

74. A device according to claim 46, wherein:
said direction of said cutting edge is arranged to not intersect said longitudinal axis.

75. A device according to claim 46, wherein:
said distal end forms only one said opening which is in communication with said cavity.

76. A device according to claim 75, wherein:
said cutting edge is arranged at farthest distal position of said hollow cannula.

77. A device according to claim 76, wherein:
said hollow cannula has an annular wall that surrounds said cavity, said cutting edge being formed in said annular wall, said annular wall having a radially inside surface and a radially outside surface;
said cutting edge is positioned at said annular wall radially spaced from said outside surface of said annular wall.

78. A device according to claim 77, wherein:
a radial distance between said cutting edge and said inside surface is less than or equal to a quarter of a radial distance between said cutting edge and said outer surface of said annular wall.

* * * * *

# EXHIBIT "G"

Int. Cls.: 9, 10 and 42

Prior U.S. Cls.: 21, 23, 26, 36, 38, 39, 44, 100 and 101

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FOR: OPTICAL WAVE GUIDES AND GLASS FIBRE CABLES; APPARATUS AND INSTRUMENTS FOR USE IN MEDICINE, NAMELY, APPARATUS FOR RECORDING, TRANSMITTING AND REPRODUCING SOUND OR IMAGES, CABLES AND FIBRES FOR THE TRANSMISSION OF SOUND AND IMAGES, ELECTRONIC APPARATUS, NAMELY, STAND ALONE DISPLAYS FOR MEDICAL IMAGES; CAMERAS– FASTENING AND GUIDING SYSTEMS FOR CAMERAS, COMPRISED OF AN ELECTRICAL, MECHANICAL OR ELECTRO-PNEUMATICAL JOINTED TRIPOD FOR HOLDING AND GUIDING CAMERAS; COMPUTER MONITORS; VIDEO MONITORS; VOICE DISPLAY MONITORS; TOUCH SCREEN MONITORS; SCOPES NAMELY, BORESCOPES; DATA PROCESSORS AND COMPUTERS; CENTRAL PROCESSING UNITS FOR PROCESSING INFORMATION, DATA, SOUND OR IMAGES, NAMELY, APPARATUS FOR THE COMPUTER-ASSISTED DOCUMENTATION OF IMAGES; COMPUTER HARDWARE AND SOFTWARE FOR USE IN OPERA TING VOICE ACTIVATED SYSTEMS; COMPUTER HARDWARE AND SOFTWARE FOR USE IN OPERATING VOICE-ACTIVATED SYSTEMS FOR USE IN MEDICINE, IN CLASS 9 (U.S. CLS. 21, 23, 26, 36 AND 38).

FOR: SURGICAL, MEDICAL, DENTAL AND VETERINARY APPARATUS AND INSTRUMENTS FOR USE IN GENERAL SURGERY AND FOR USE IN ENDOSCOPY; APPARATUS AND INSTRUMENTS FOR SURGICAL, DENTAL AND VETERINARY PURPOSES, NAMELY, ENDOSCOPY CAMERAS, SURGICAL KNIVES, SURGICAL SCALPELS, SURGICAL BLADES, SURGICAL STAPLERS, SURGICAL SCISSORS, SURGICAL SAWS, MEDICAL CUTTING DEVICES, SURGICAL CUTLERY, SURGICAL SUTURES, LASERS FOR SURGICAL AND MEDICAL USE, APPARATUS FOR REMOVAL OF HERNIATED VERTEBRAL DISCS, SURGICAL TROCARS, SURGICAL GUIDE PIPES, SURGICAL GUIDE WIRES, SURGICAL GUIDE HOSES, SURGICAL CANNULAS, NEEDLES FOR MEDICAL USE, SURGICAL REAMERS, DRILLS FOR SURGICAL AND DENTAL USE, SURGICAL APPLICATORS, SURGICAL CHISELS, SURGICAL PUNCHES, SURGICAL WATER JET CUTTERS; ENDOSCOPIC APPARATUS; FASTENING AND GUIDING SYSTEMS FOR ENDOSCOPES COMPRISED OF AN ELECTRICAL, MECHANICAL OR ELECTRO-PNEUMATICAL JOINTED TRIPOD FOR HOLDING AND GUIDING ENDOSCOPES; MEDICAL APPARATUS AND INSTRUMENTS FOR DETECTING NUCLIDES; MEDICAL PUMPS, NAMELY, IRRIGATORS FOR MEDICAL USE, SUCKERS FOR MEDICAL USE; INSUFFLATORS; APPARATUS FOR DISPENSING DISSOLUTIONS OF CARBON DIOXIDE SCRUBBING; MEDICAL WATERJET INCISION AND REMOVAL APPARATUS; MEDICAL SUTURE INSTRUMENTS; MEDICINAL IMPLANTS CONSISTING OF ARTIFICIAL MATERIALS, NAMELY, BONE IMPLANTS, BLOOD VESSEL IMPLANTS, BLOOD VESSEL VALVE IMPLANTS, SUTURE IMPLANTS, POLYMER CLIPS, SUTURE IMPLANTS MADE OF NITINOL AND TITANIUM, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FOR: SCIENTIFIC RESEARCH AND INDUSTRIAL RESEARCH IN THE FIELDS OF MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE; RESEARCH AND DEVELOPMENT OF NEW PRODUCTS FOR OTHERS IN THE FIELD OF MEDICAL APPARATUS AND INSTRUMENTS AS WELL AS IN THE FIELD OF PHARMACEUTICAL PREPARATIONS AND MEDICINES; MEDICAL AND SCIENTIFIC RESEARCH, NAMELY CONDUCTING CLINICAL TRIALS OF MEDICAL APPARATUS, INSTRUMENTS AND OTHER MEDICAL PRODUCTS, IN CLASS 42 (U.S. CLS. 100 AND 101).

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF INTERNATIONAL REGISTRATION 0817935A DATED 7-1-2003, EXPIRES 7-1-2013.

SER. NO. 79-012,567, FILED 4-7-2005.

WENDY JUN, EXAMINING ATTORNEY

# EXHIBIT "H"

Int. Cls.: 9, 10 and 42

Prior U.S. Cls.: 21, 23, 26, 36, 38, 39, 44, 100 and 101

United States Patent and Trademark Office

Reg. No. 3,619,500

Registered May 12, 2009

TRADEMARK
SERVICE MARK
PRINCIPAL REGISTER

# Tessys

JOIMAX GMBH (FED REP GERMANY GMBH)
AMALIENBADSTRAßE 36
76227 KARLSRUHE
FED REP GERMANY

FOR: SCIENTIFIC, NAUTICAL, SURVEYING, PHOTOGRAPHIC, CINEMATOGRAPHIC, WEIGHING, MEASURING, SIGNALING, CHECKING, SUPERVISION, LIFE-SAVING AND TEACHING APPARATUS AND INSTRUMENTS, PARTICULARLY INTEGRATED APPARATUS FOR REPRODUCING AND PROCESSING IMAGES AND SYSTEMS COMPOSED OF THE ABOVE APPARATUS, NAMELY, CAMERAS, CENTRAL PROCESSING UNITS FOR PROCESSING INFORMATION, DATA, SOUND OR IMAGES, CABLES AND FIBRES FOR THE TRANSMISSION OF SOUND AND IMAGES, OPTICAL WAVE GUIDES, OPTICAL GLASS FIBRE CABLES, WEIGHING EQUIPMENT, NAMELY, SCALES AND BALANCES; ELECTRONIC APPARATUS, NAMELY, STAND ALONE DISPLAYS FOR MEDICAL IMAGES; APPARATUS FOR RECORDING, TRANSMISSION OR REPRODUCTION OF SOUND, IMAGES AND DATA; RECORDING MEDIA, NAMELY, BLANK MAGNETIC DATA CARRIERS, BLANK MAGNETIC COMPUTER TAPES, MAGNETIC CARDS, PRE-RECORDED MAGNETIC DATA CARRIERS FEATURING MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE, BLANK CD-ROMS AND DVD-ROMS FOR SOUND, IMAGE OR VIDEO RECORDING, PRERECORDED CD'S, VIDEO TAPES, LASER DISKS AND DVD'S FEATURING MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE; DATA PROCESSING EQUIPMENT AND COMPUTERS; COMPUTER SOFTWARE FOR USE IN OPERATING VOICE-ACTIVATED SYSTEMS FOR USE IN MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE; COMPUTER SOFTWARE FOR USE IN DATA BASE MANAGEMENT FOR USE IN MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE; COMPUTER SOFTWARE FOR THE COLLECTION, EDITING, ORGANIZING, MODIFYING, BOOK MARKING, TRANSMISSION, STORAGE AND SHARING OF DATA AND INFORMATION FOR USE IN MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE; COMPUTER SOFTWARE FOR CONTROLLING AND MANAGING PATIENT MEDICAL INFORMATION, FOR USE IN MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE; MEDICAL SOFTWARE FOR PROCESSING AND DISPLAYING IMAGES ON ULTRASOUND MEDICAL IMAGING MACHINES, FOR USE IN MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE, IN CLASS 9 (U.S. CLS. 21, 23, 26, 36 AND 38).

FOR: SURGICAL, MEDICAL, DENTAL AND VETERINARY APPARATUS AND INSTRUMENTS, NAMELY, ENDOSCOPY CAMERAS, SURGICAL KNIVES, SURGICAL SCALPELS, SURGICAL BLADES, SURGICAL STAPLERS, SURGICAL SCISSORS, SURGICAL SAWS, MEDICAL CUTTING DEVICES, SURGICAL CUTLERY, SURGICAL SUTURES, LASERS FOR SURGICAL AND MEDICAL USE, APPARATUS FOR REMOVAL OF HERNIATED VERTEBRAL DISCS, SURGICAL TROCARS, SURGICAL GUIDE PIPES, SURGICAL GUIDE WIRES, SURGICAL GUIDE HOSES, SURGICAL CANNULAS, NEEDLES FOR MEDICAL USE, SURGICAL REAMERS, DRILLS FOR SURGICAL AND DENTAL USE, SURGICAL APPLICATORS, SURGICAL CHISELS, SURGICAL PUNCHES, SURGICAL WATER JET CUTTERS; APPARATUS AND INSTRUMENTS FOR SURGICAL AND VETERINARY PURPOSES FOR USE IN GENERAL SURGERY, FOR USE IN ENDOSCOPY; SUTURE MATERIALS, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FOR: DESIGN AND DEVELOPMENT OF COMPUTER HARDWARE AND SOFTWARE; INDUSTRIAL ANALYSIS AND RESEARCH SERVICES IN

THE FIELDS OF MEDICINE, SURGERY, DENTISTRY AND VETERINARY MEDICINE; SCIENTIFIC, TECHNOLOGICAL AND DEVELOPMENT SERVICES, NAMELY, MEDICAL AND SCIENTIFIC RESEARCH, NAMELY, CONDUCTING CLINICAL TRIALS OF MEDICAL APPARATUS, INSTRUMENTS AND OTHER MEDICAL PRODUCTS; RESEARCH AND DEVELOPMENT ACTIVITIES NAMELY, RESEARCH AND DEVELOPMENT OF NEW PRODUCTS FOR OTHERS IN THE FIELD OF MEDICAL APPARATUS AND INSTRUMENTS AS WELL AS IN THE FIELD OF PHARMACEUTICAL PREPARATIONS AND MEDICINES; CONSTRUCTION DRAFTING AND RELATED DESIGN, IN CLASS 42 (U.S. CLS. 100 AND 101).

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

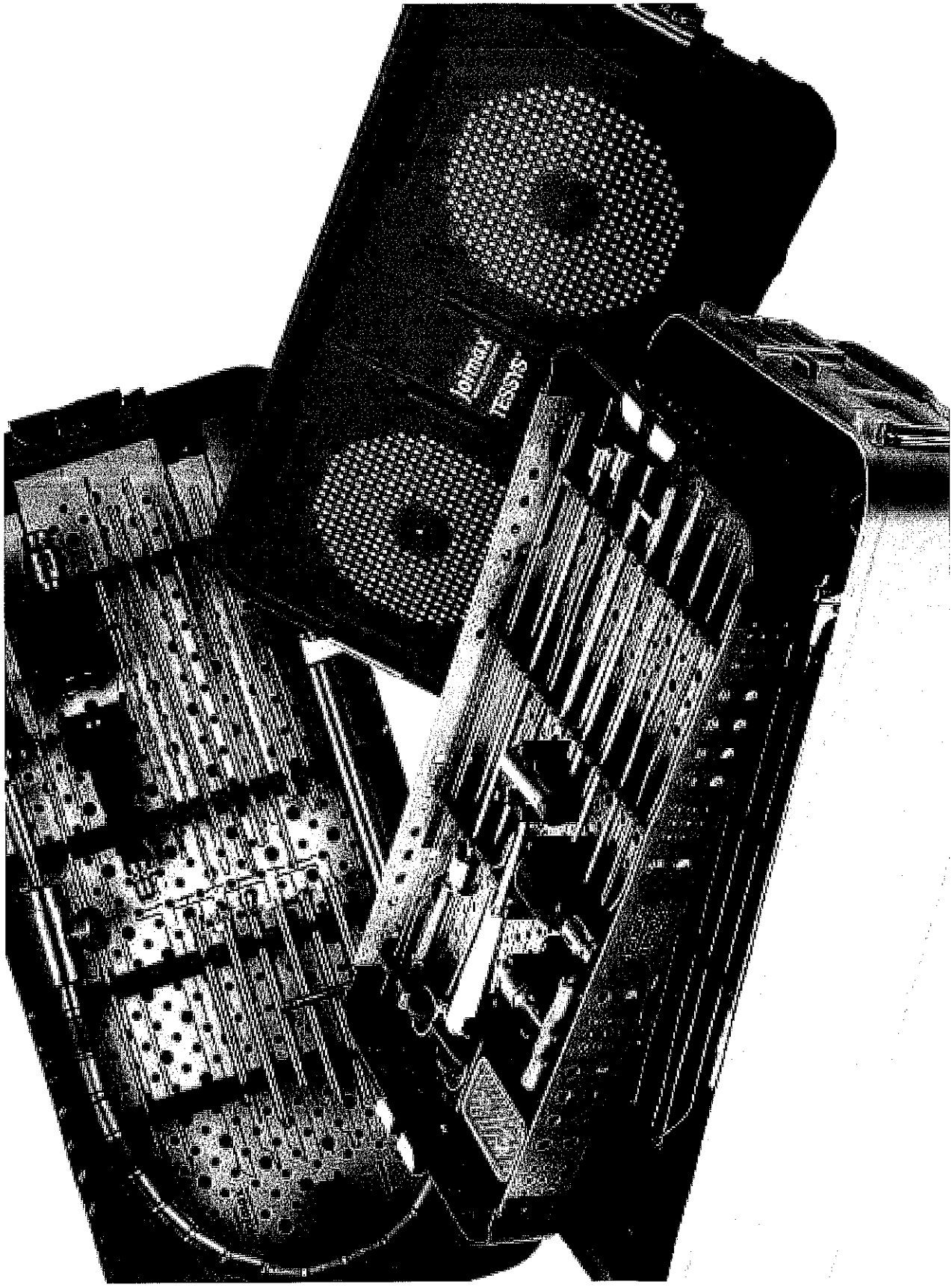
PRIORITY DATE OF 4-13-2007 IS CLAIMED.

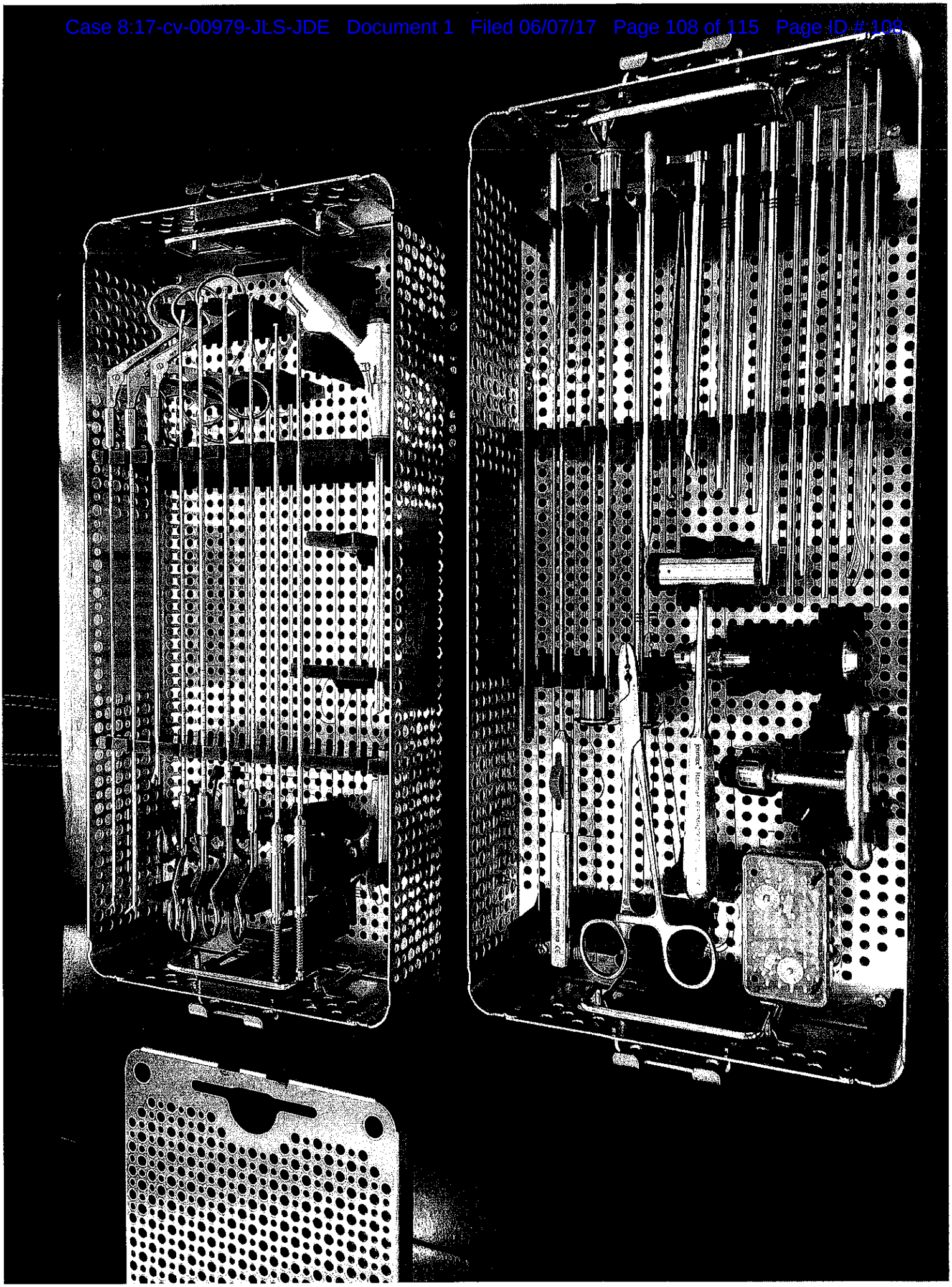
OWNER OF INTERNATIONAL REGISTRATION 0943230 DATED 10-5-2007, EXPIRES 10-5-2017.

SER. NO. 79-046,113, FILED 10-5-2007.

SAIMA MAKHDOOM, EXAMINING ATTORNEY

# EXHIBIT "I"


Johnson
Tech



joimax®

# Disposable Access Kit for joimax® Endoscopic Surgical Systems

**TESSYS®** Transforaminal Endoscopic Surgical System | **iLESSYS®** Interlaminar Endoscopic Surgical System | **CESSYS®** Cervical Endoscopic Surgical System | **intENTS®** Intradiscal Endoscopic Nucleus Therapy Set | **Multiuse RT** Endoscopic Multipurpose Rhizotomy Set

**STERILE FOR SINGLE USE ONLY**

# EXHIBIT "J"